

US3362116 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:16:22

All time stamps listed in this document are displayed in GMT

US3362116

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

[Participant ID](#)

US3362116

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

US3362116

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362116

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3362116

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3362116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3362116

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Were any significant conditions reported?

Yes ☒

No ☐

US3362116

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	20 DEC 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)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3362116

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	20 DEC 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 DEC 2016
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	DEC 2016
Stop Year (derived)	2016

US3362116

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	L4-L5 S1 FUSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3362116

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362116

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	DRUG ALLERGY - MORPHINE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3362116

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	CHRONIC NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3362116

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	DEGENERATIVE DISC DISEASE OF L4-L5,L5-S1
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3362116

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Condition	ABDOMINAL HERNIA
Start date (dd MMM yyyy)	18 OCT 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)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3362116

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 10:36
Height (<i>xxx.x</i>)	175.6 cm
Weight (<i>xxx.x</i>)	92.8 kg
BMI (<i>xxx.x</i>)	30.09532 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362116

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3362116

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3362116

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:17:23

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 143617

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 ☒

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Height	ND - Not Done
Weight	ND - Not Done

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

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)	12 AUG 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 10:36
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

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)	12 AUG 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:15
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3362116

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 11:39

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

US3362116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 AUG 2020

Collection time (00:00-23:59)

11:15 (24 HR)

Collection date and time (derived)

12 AUG 2020 11:15

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:57	12 AUG 2020 10:57
Nasopharyngeal Swab 2	No		

US3362116

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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

98.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp 12 AUG 2020 12:12

PC Open Date & Time 12 AUG 2020 11:59

PC Close Date & Time 12 AUG 2020 14:29

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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 98.2 °F

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

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

PC Time Stamp	12 AUG 2020 17:53
PC Open Date & Time	12 AUG 2020 15:24
PC Close Date & Time	13 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:39

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 17:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 16:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 21:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 15:41

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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

12 AUG 2020 12:13

PC Open Date & Time

12 AUG 2020 11:59

PC Close Date & Time

12 AUG 2020 14:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 17:54

PC Open Date & Time

12 AUG 2020 15:24

PC Close Date & Time

13 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

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

13 AUG 2020 12:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

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

14 AUG 2020 17:39

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

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

15 AUG 2020 17:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

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

16 AUG 2020 16:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

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

17 AUG 2020 21:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

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

18 AUG 2020 15:41

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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 ☐

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 12:14
PC Open Date & Time	12 AUG 2020 11:59
PC Close Date & Time	12 AUG 2020 14:29

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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 ☐

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 17:54
PC Open Date & Time	12 AUG 2020 15:24
PC Close Date & Time	13 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2294

EAB) (1725)

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

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

52 of 2294

EAB) (1725)

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 17:40
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

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

54 of 2294

EAB) (1725)

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

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

56 of 2294

EAB) (1725)

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

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 ☒

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:25
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

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)

60 of 2294

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 15:41
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 06:59

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 06:59
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3362116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	10:49 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:49
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:11
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3362116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 11:40

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

US3362116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	11:07 (24 HR)
Collection date and time (derived)	18 SEP 2020 11:07

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	18 SEP 2020 11:06
Nasopharyngeal Swab 2	No		

US3362116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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

98.5 °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

18 SEP 2020 12:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 14:30

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	18 SEP 2020 19:53
PC Open Date & Time	18 SEP 2020 15:25
PC Close Date & Time	19 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

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

99.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 SEP 2020 12:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	20 SEP 2020 14:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

21 SEP 2020 13:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:30

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 14:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

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

24 SEP 2020 13:12

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 14:30

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 19:53

PC Open Date & Time

18 SEP 2020 15:25

PC Close Date & Time

19 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 14:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:30

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 14:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:13

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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 ☐

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 12:17
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 14:30

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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 ☐

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 19:54
PC Open Date & Time	18 SEP 2020 15:25
PC Close Date & Time	19 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

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 ☒

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

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)

106 of 2294

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

		Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 14:04	
PC Open Date & Time	20 SEP 2020 12:00	
PC Close Date & Time	21 SEP 2020 11:59	

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

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 ☒

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:25
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

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)

110 of 2294

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:31
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

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)

112 of 2294

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 14:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

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 ☒

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:13
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3362116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:26

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

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

Visit date (dd MMM yyyy)	14 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
------------	--------

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:21
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3362116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

11:31 (24 HR)

Collection date and time (derived)

14 OCT 2020 11:31

US3362116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:03:27

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 00:07:12
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 22:01:19

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 08:00:49

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 05:18:15

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 06:38:21
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 07:43:03

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 12:01:57
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 11:55:08

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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 ☒

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 DEC 2020 00:02:06

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:43:44

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 00:02:08

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 00:09:09

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 JAN 2021 00:42:59
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 JAN 2021 00:07:46
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 JAN 2021 00:10:32
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 JAN 2021 12:09:47
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 00:40:57

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:03:08
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 00:04:19
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 07:26:01
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 00:09:01

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 00:04:05

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 04:51:25

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 12:07:42

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 17:59:18

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 11:59:28

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 10:11:30

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 06:25:40

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:02:34

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3362116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:16:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 00:09:13

US3362116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:20:22

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:20:22

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3362116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3362116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

09:09 (24 HR)

Collection date and time (derived)

3 MAR 2021 09:09

US3362116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:14:40

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362116

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3362116

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362116

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:16:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3362116

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3362116

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

Date of updated informed consent (dd MMM yyyy) 27 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 27 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3362116

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

27 JAN 2021 09:08

US3362116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	09:13
Collection Date and Time (derived)	27 JAN 2021 09:13

US3362116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:13:30

Generated On: 09 Jun 2021 17:16:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

LOWER BACK MUSCLE STRAIN

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

333 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

SORE THROAT (PHARYNGITIS)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

335 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

CHILLS

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)

19 SEP 2020

Start time (00:00-23:59)

04:30 (24 HR)

AE start date and time (derived)

19 SEP 2020 04:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 SEP 2020

End time (00:00-23:59)

10:00 (24 HR)

AE End Date and Time (derived)

20 SEP 2020 10:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

337 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

GENERALIZED MYALGIAS

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)

19 SEP 2020

Start time (00:00-23:59)

04:30 (24 HR)

AE start date and time (derived)

19 SEP 2020 04:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 SEP 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

21 SEP 2020 08:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

339 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

WORSENING OF CHRONIC
NECK PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 SEP 2020

Start time (00:00-23:59)

04:30 (24 HR)

AE start date and time (derived)

19 SEP 2020 04:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 SEP 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

21 SEP 2020 08:00

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

341 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

HEADACHE

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)

19 SEP 2020

Start time (00:00-23:59)

04:30 (24 HR)

AE start date and time (derived)

19 SEP 2020 04:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 SEP 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

21 SEP 2020 08:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

343 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

EAR INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

5 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

345 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID	USA-US112-2021-MRNA-1273-P30 1000009
Adverse event	CELLULITIS OF LEFT ABDOMEN
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)	30 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	02 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	347 of 2294

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

PER PATIENT, PATIENT WENT
FOR ROUTINE HERNIA REPAIR
ON 21JAN2021. PATIENT
DEVELOPED BACTERIAL
INFECTION OF LEFT ABDOMEN
AS COMPLICATION FROM
PROCEDURE. PATIENT WAS
HOSPITALIZED AND TREATED
FOR A STAPHYLOCOCCUS
INFECTION. PATIENT WAS
DISCHARGED ON 02FEB2021.
MEDICAL RECORDS
REQUESTED. SAE ENTERED IN
EDC.

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

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

350 of 2294

EAB) (1725)

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

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

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:51:08

Generated On: 09 Jun 2021 17:16:22

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

Yes ☒

No ☐

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

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NECK PAIN

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)

353 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

355 of 2294

EAB) (1725)

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2016	
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"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

357 of 2294

EAB) (1725)

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2016	
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"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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)

359 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication MOBIC

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK MUSCLE STRAIN

Dose per administration 15

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

361 of 2294

EAB) (1725)

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	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)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PHARYNGITIS

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)

363 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	21 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF CHRONIC
NECK PAIN AND GENERALIZED
MYALGIAS.

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)

365 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	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)	20 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication EAR INFECTION

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)

367 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication EAR INFECTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

Name of Medication BACTRIM DS

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS OF LEFT
ABDOOMEN

Dose per administration 800/160

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:51:07

Generated On: 09 Jun 2021 17:16:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:51:08

Generated On: 09 Jun 2021 17:16:22

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:51:08

Generated On: 09 Jun 2021 17:16:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	HERNIA REPAIR	Medical History	

US3362116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:16:22

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3362116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:22

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

SAEID	USA-US112-2021-MRNA-1273-P301000009
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

SAEID	USA-US112-2021-MRNA-1273-P301000009
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/FEB/2021 14:54
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

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

SAEID	USA-US112-2021-MRNA-1273-P301000009
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:54
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

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:16:22

SAEID	USA-US112-2021-MRNA-1273-P301000009
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/MAR/2021 09:19
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

US3362116 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362116

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:22

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'US3362116'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:19:34

US3362116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:08

US3362116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:19:35

US3362116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:08

US3362116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'SCRN'	System	12 Aug 2020 19:58:08

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:19:37

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '56'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'YEARS'	System	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '56'	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'I'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:22

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:58:24

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Aug 2020'	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2020'	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:19:35

US3362116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'I'	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:16:22

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:40:56

US3362116

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:16:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 19:59:07

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User closed query 'Per DM CLR: Please review the status of this condition as a procedure for this condition has been recorded (MH# 2). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:05:28
Query 'Per DM CLR: Please review the status of this condition as a procedure for this condition has been recorded (MH# 2). ' answered with 'DISEASE IS ONGOING. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 21:18:17
User opened query 'Per DM CLR: Please review the status of this condition as a procedure for this condition has been recorded (MH# 2). ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:57:35
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:04:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:04:18
Data point term sent to Coder	System	12 Aug 2020 20:03:18
User entered 'Coronary Artery Disease'	(b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '20 Dec 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Dec 2016'	System	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2016'	System	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:02:19

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 20:04:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 20:04:18
Data point term sent to Coder	System	12 Aug 2020 20:03:18
User entered 'Stent Placement'	(b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '20 Dec 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '20 Dec 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Dec 2016'	System	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2016'	System	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Dec 2016'	System	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2016'	System	12 Aug 2020 20:02:43

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User closed query 'Per CDM re-query: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:38:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 07:00:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 07:00:23
Query 'Per CDM re-query: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:22:15
User opened query 'Per CDM re-query: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:06:22
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:06:10
Data point term sent to Coder	System	02 Oct 2020 21:16:48
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 21:16:27
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 21:16:22
User entered 'L4-L5 S1 FUSION' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Oct 2020 21:16:22

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:58:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 11:35:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	17 Aug 2020 11:35:06
Data point term sent to Coder	System	12 Aug 2020 20:03:18
User entered 'Lower Back Surgery'	(b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2010'	System	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2010'	System	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2010'	System	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2010'	System	12 Aug 2020 20:03:09

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:46:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'CHRONIC NECK PAIN IS LISTED IN MED HISTORY ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 20:57:46
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:58:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:05:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:05:09
Data point term sent to Coder	System	12 Aug 2020 20:04:22
User entered 'Neck Surgery'	(b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2018'	System	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2018'	System	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2018'	System	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2018'	System	12 Aug 2020 20:03:39

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 20:07:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 20:07:24
Data point term sent to Coder	System	12 Aug 2020 20:06:27
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 13:34:00
User entered 'UN UNK 2018'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2016'	System	05 Sep 2020 13:34:00
User entered 'Jan 2018'	System	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2016'	System	05 Sep 2020 13:34:00
User entered '2018'	System	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:05:59

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 05:55:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 05:55:12
Data point term sent to Coder	System	12 Aug 2020 20:06:27
User entered 'Drug Allergy - Morphine'	(b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2000'	System	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2000'	System	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	12 Aug 2020 20:06:16

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:45:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:45:34
Data point term sent to Coder	System	25 Aug 2020 18:44:49
User entered 'CHRONIC NECK PAIN'	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2018'	System	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2018'	System	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	25 Aug 2020 18:44:06

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 14:48:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 14:48:34
Data point term sent to Coder	System	09 Oct 2020 14:23:33
User entered 'Degenerative Disc Disease of L4-L5,L5-S1'	(b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2018'	System	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2018'	System	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Jan 2018'	System	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2018'	System	09 Oct 2020 14:23:13

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 21:22:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 21:22:06
Data point term sent to Coder	System	06 Mar 2021 21:21:25
User entered 'abdominal hernia'	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '18 Oct 2019'	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	Amy Thomassie (b) (4)	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'Oct 2019'	System	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '2019'	System	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered empty.	System	06 Mar 2021 21:21:18

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
Query 'Per CDM: Please confirm if time 10:36 is AM or PM. Thank you!' canceled (Site from DM).	(b) (4)	25 Sep 2020 10:29:41
User opened query 'Per CDM: Please confirm if time 10:36 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:42:15
User entered '10:36'		12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered '12 Aug 2020 10:36'	System	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '175.6' cm	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:04
DataPoint set to visible.	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '92.8' kg	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:04
DataPoint set to visible.	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
Amendment Manager: User entered '30.09532'	System	16 Sep 2020 23:53:27
User entered '30.1'	System	12 Aug 2020 20:00:04
DataPoint set to visible.	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'kg/m2'	System	12 Aug 2020 20:00:04
DataPoint set to visible.	System	12 Aug 2020 16:41:12

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered '36.7' C reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 12:44:50
User entered '3.7' C	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered '80'	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'bpm'	System	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered '18'	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'breaths/min'	System	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered '138'	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'mmHg'	System	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:23
User entered '92'	(b) (4), (b) (6)	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User entered 'mmHg'	System	12 Aug 2020 20:00:04

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58

US3362116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58

US3362116

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:49

US3362116

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:00:49

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:58
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:17:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:01:23

US3362116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:29

US3362116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:29

US3362116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:06:29

US3362116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'VISIT1'	System	12 Aug 2020 20:06:29

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:19:56

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:51:35
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:51:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:19:56
User entered '143617' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:19:56

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:19:56

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:07:00

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:07:00

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:07:00

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:07:00

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:07:00

US3362116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:22

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:30:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:45:44

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '175.6' cm	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '92.8' kg	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '175.6' cm	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '92.8' kg	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '10:36'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered '12 Aug 2020 10:36'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '80'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'bpm'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'breaths/min'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '138'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'mmHg'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '92'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'mmHg'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '175.6' cm	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:48
User entered '92.8' kg	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12:15' reason for change: Data Entry Error	(b) (4)	05 Sep 2020 13:40:21
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Amy Thomassie (b) (4)	17 Aug 2020 10:22:34
User entered '12:17' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:25:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, vitals taken after 30 mins.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 20:11:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 20:11:03
User entered '12:15'	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered '12 Aug 2020 12:15'	System	05 Sep 2020 13:40:21
User entered '12 Aug 2020 12:17'	System	12 Aug 2020 20:25:36
User entered '12 Aug 2020 12:15'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '82'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'bpm'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'breaths/min'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '145' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:25:36
User entered '141'	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'mmHg'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Aug 2020 20:25:36
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	12 Aug 2020 20:25:36
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:25:36
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Aug 2020 20:11:03
User entered '102'	(b) (4), (b) (6)	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'mmHg'	System	12 Aug 2020 20:11:03

US3362116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:16:42

US3362116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:16:42

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:39'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered '12 Aug 2020 11:39'	System	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'ONCE'	System	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 16:41:36

US3362116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:18

US3362116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:18

US3362116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:15'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:18

US3362116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered '12 Aug 2020 11:15'	System	12 Aug 2020 20:17:18

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '10:57'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered '12 Aug 2020 10:57'	System	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered empty.	System	12 Aug 2020 20:17:38

US3362116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:17:45

US3362116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	12 Aug 2020 20:17:45

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:12:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '2e367092-0135-4266-bce6-b80c3d7cf348'	System	12 Aug 2020 17:12:43
User entered 'Yes (Y)'	System	12 Aug 2020 17:12:43

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:12:26', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '2e367092-0135-4266-bce6-b80c3d7cf348'	System	12 Aug 2020 17:12:43
User entered '98.5'	System	12 Aug 2020 17:12:43

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:12:32', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '2e367092-0135-4266-bce6-b80c3d7cf348'	System	12 Aug 2020 17:12:43
User entered 'No (N)'	System	12 Aug 2020 17:12:43

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:12:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '2e367092-0135-4266-bce6-b80c3d7cf348'	System	12 Aug 2020 17:12:43
User entered '12 Aug 2020 12:12'	System	12 Aug 2020 17:12:43

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 14:29'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:53:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ccd91e5b-5cc3-42fe-b0f5-b88b0c993d71' User entered 'Yes (Y)'	System	12 Aug 2020 22:53:26
	System	12 Aug 2020 22:53:26

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:53:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ccd91e5b-5cc3-42fe-b0f5-b88b0c993d71' User entered '98.2'	System	12 Aug 2020 22:53:26
	System	12 Aug 2020 22:53:26

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:53:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ccd91e5b-5cc3-42fe-b0f5-b88b0c993d71' User entered 'No (N)'	System	12 Aug 2020 22:53:26
	System	12 Aug 2020 22:53:26

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:53:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ccd91e5b-5cc3-42fe-b0f5-b88b0c993d71' User entered '12 Aug 2020 17:53'	System	12 Aug 2020 22:53:26
	System	12 Aug 2020 22:53:26

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 15:24'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 2'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:04:20', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1c363c5f-c1cd-4367-ab51-84c996078acb' User entered 'Yes (Y)'	System	13 Aug 2020 17:06:10
	System	13 Aug 2020 17:06:10

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:05:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1c363c5f-c1cd-4367-ab51-84c996078acb' User entered '95.8'	System	13 Aug 2020 17:06:10
	System	13 Aug 2020 17:06:10

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1c363c5f-c1cd-4367-ab51-84c996078acb' User entered 'No (N)'	System	13 Aug 2020 17:06:10
	System	13 Aug 2020 17:06:10

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1c363c5f-c1cd-4367-ab51-84c996078acb' User entered '13 Aug 2020 12:06'	System	13 Aug 2020 17:06:10
	System	13 Aug 2020 17:06:10

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 3'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:34', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '01bfea26-f731-450e-a579-23952ed7f4a3' User entered 'Yes (Y)'	System	14 Aug 2020 22:39:50
	System	14 Aug 2020 22:39:50

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:41', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '01bfea26-f731-450e-a579-23952ed7f4a3' User entered '97.2'	System	14 Aug 2020 22:39:50
	System	14 Aug 2020 22:39:50

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '01bfea26-f731-450e-a579-23952ed7f4a3'	System	14 Aug 2020 22:39:50
User entered 'No (N)'	System	14 Aug 2020 22:39:50

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '01bfea26-f731-450e-a579-23952ed7f4a3' User entered '14 Aug 2020 17:39'	System	14 Aug 2020 22:39:50
	System	14 Aug 2020 22:39:50

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 4'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:30:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7235d074-169e-4f4d-b124-0226853b6f60' User entered 'Yes (Y)'	System	15 Aug 2020 22:31:02
	System	15 Aug 2020 22:31:02

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:30:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7235d074-169e-4f4d-b124-0226853b6f60' User entered '97.8'	System	15 Aug 2020 22:31:02
	System	15 Aug 2020 22:31:02

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:30:58', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7235d074-169e-4f4d-b124-0226853b6f60' User entered 'No (N)'	System	15 Aug 2020 22:31:02
	System	15 Aug 2020 22:31:02

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7235d074-169e-4f4d-b124-0226853b6f60' User entered '15 Aug 2020 17:31'	System	15 Aug 2020 22:31:02
	System	15 Aug 2020 22:31:02

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 5'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:11:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7ca1790c-7a0e-4c82-b646-9788b98e31ee' User entered 'Yes (Y)'	System	16 Aug 2020 21:12:11
	System	16 Aug 2020 21:12:11

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7ca1790c-7a0e-4c82-b646-9788b98e31ee' User entered '95.7'	System	16 Aug 2020 21:12:11
	System	16 Aug 2020 21:12:11

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7ca1790c-7a0e-4c82-b646-9788b98e31ee' User entered 'No (N)'	System	16 Aug 2020 21:12:11
	System	16 Aug 2020 21:12:11

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7ca1790c-7a0e-4c82-b646-9788b98e31ee' User entered '16 Aug 2020 16:12'	System	16 Aug 2020 21:12:11
	System	16 Aug 2020 21:12:11

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 6'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'df425c22-e9e0-44c3-a3b4-1fed33e8de73' User entered 'Yes (Y)'	System	18 Aug 2020 02:24:30
	System	18 Aug 2020 02:24:30

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'df425c22-e9e0-44c3-a3b4-1fed33e8de73' User entered '97.3'	System	18 Aug 2020 02:24:30
	System	18 Aug 2020 02:24:30

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'df425c22-e9e0-44c3-a3b4-1fed33e8de73'	System	18 Aug 2020 02:24:30
User entered 'No (N)'	System	18 Aug 2020 02:24:30

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'df425c22-e9e0-44c3-a3b4-1fed33e8de73'	System	18 Aug 2020 02:24:30
User entered '17 Aug 2020 21:24'	System	18 Aug 2020 02:24:30

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 7'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:40:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b36227f-6dff-43aa-8024-42f2f236b4b3' User entered 'Yes (Y)'	System	18 Aug 2020 20:41:05
	System	18 Aug 2020 20:41:05

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:40:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b36227f-6dff-43aa-8024-42f2f236b4b3' User entered '97.9'	System	18 Aug 2020 20:41:05
	System	18 Aug 2020 20:41:05

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b36227f-6dff-43aa-8024-42f2f236b4b3'	System	18 Aug 2020 20:41:05
User entered 'No (N)'	System	18 Aug 2020 20:41:05

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b36227f-6dff-43aa-8024-42f2f236b4b3' User entered '18 Aug 2020 15:41'	System	18 Aug 2020 20:41:05
	System	18 Aug 2020 20:41:05

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:12:59', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3e95c9a8-6222-42df-be71-33b23a685182' User entered 'None (1)'	System	12 Aug 2020 17:13:44
	System	12 Aug 2020 17:13:44

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3e95c9a8-6222-42df-be71-33b23a685182' User entered 'No (N)'	System	12 Aug 2020 17:13:44
	System	12 Aug 2020 17:13:44

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:20', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3e95c9a8-6222-42df-be71-33b23a685182'	System	12 Aug 2020 17:13:44
User entered 'No (N)'	System	12 Aug 2020 17:13:44

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:35', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3e95c9a8-6222-42df-be71-33b23a685182'	System	12 Aug 2020 17:13:44
User entered 'None (1)'	System	12 Aug 2020 17:13:44

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3e95c9a8-6222-42df-be71-33b23a685182' User entered '12 Aug 2020 12:13'	System	12 Aug 2020 17:13:44
	System	12 Aug 2020 17:13:44

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 14:29'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:53:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a6bc87f5-991b-4819-8c6d-78696092650d'	System	12 Aug 2020 22:54:29
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:54:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a6bc87f5-991b-4819-8c6d-78696092650d' User entered 'No (N)'	System	12 Aug 2020 22:54:29
	System	12 Aug 2020 22:54:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a6bc87f5-991b-4819-8c6d-78696092650d' User entered 'No (N)'	System	12 Aug 2020 22:54:29
	System	12 Aug 2020 22:54:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:21', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a6bc87f5-991b-4819-8c6d-78696092650d' User entered 'None (1)'	System	12 Aug 2020 22:54:29
	System	12 Aug 2020 22:54:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a6bc87f5-991b-4819-8c6d-78696092650d' User entered '12 Aug 2020 17:54'	System	12 Aug 2020 22:54:29
	System	12 Aug 2020 22:54:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 15:24'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 2'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '546b8ea0-6b8e-4f41-9834-b557fd6cf083'	System	13 Aug 2020 17:06:59
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 17:06:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:24', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '546b8ea0-6b8e-4f41-9834-b557fd6cf083' User entered 'No (N)'	System	13 Aug 2020 17:06:59
	System	13 Aug 2020 17:06:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '546b8ea0-6b8e-4f41-9834-b557fd6cf083'	System	13 Aug 2020 17:06:59
User entered 'No (N)'	System	13 Aug 2020 17:06:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:47', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '546b8ea0-6b8e-4f41-9834-b557fd6cf083'	System	13 Aug 2020 17:06:59
User entered 'None (1)'	System	13 Aug 2020 17:06:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:06:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '546b8ea0-6b8e-4f41-9834-b557fd6cf083'	System	13 Aug 2020 17:06:59
User entered '13 Aug 2020 12:06'	System	13 Aug 2020 17:06:59

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 3'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:38:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04efecdf-acc-490c-8e3f-f02b5d56a23d'	System	14 Aug 2020 22:39:29
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:39:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04efecdf-acc-490c-8e3f-f02b5d56a23d'	System	14 Aug 2020 22:39:29
User entered 'No (N)'	System	14 Aug 2020 22:39:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04efecdf-acc-490c-8e3f-f02b5d56a23d'	System	14 Aug 2020 22:39:29
User entered 'No (N)'	System	14 Aug 2020 22:39:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04efecdf-acc-490c-8e3f-f02b5d56a23d'	System	14 Aug 2020 22:39:29
User entered 'None (1)'	System	14 Aug 2020 22:39:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:28', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04efecdf-acc-490c-8e3f-f02b5d56a23d'	System	14 Aug 2020 22:39:29
User entered '14 Aug 2020 17:39'	System	14 Aug 2020 22:39:29

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 4'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9b48a9ed-b480-4a49-ac91-799e456f3660'	System	15 Aug 2020 22:31:22
User entered 'None (1)'	System	15 Aug 2020 22:31:22

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9b48a9ed-b480-4a49-ac91-799e456f3660' User entered 'No (N)'	System	15 Aug 2020 22:31:22
	System	15 Aug 2020 22:31:22

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9b48a9ed-b480-4a49-ac91-799e456f3660' User entered 'No (N)'	System	15 Aug 2020 22:31:22
	System	15 Aug 2020 22:31:22

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9b48a9ed-b480-4a49-ac91-799e456f3660' User entered 'None (1)'	System	15 Aug 2020 22:31:22
	System	15 Aug 2020 22:31:22

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9b48a9ed-b480-4a49-ac91-799e456f3660'	System	15 Aug 2020 22:31:22
User entered '15 Aug 2020 17:31'	System	15 Aug 2020 22:31:22

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 5'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a597a3c3-4a5b-480b-bb90-dbdcdb7075bb' User entered 'None (1)'	System	16 Aug 2020 21:12:30
	System	16 Aug 2020 21:12:30

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a597a3c3-4a5b-480b-bb90-dbdcdb7075bb' User entered 'No (N)'	System	16 Aug 2020 21:12:30
	System	16 Aug 2020 21:12:30

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a597a3c3-4a5b-480b-bb90-dbdcdb7075bb' User entered 'No (N)'	System	16 Aug 2020 21:12:30
	System	16 Aug 2020 21:12:30

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:26', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a597a3c3-4a5b-480b-bb90-dbdcdb7075bb' User entered 'None (1)'	System	16 Aug 2020 21:12:30
	System	16 Aug 2020 21:12:30

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:28', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a597a3c3-4a5b-480b-bb90-dbdcdb7075bb' User entered '16 Aug 2020 16:12'	System	16 Aug 2020 21:12:30
	System	16 Aug 2020 21:12:30

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 6'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:30', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7dde1815-3a94-40c0-ab0c-d6acb5eb47ed' User entered 'None (1)'	System	18 Aug 2020 02:24:47
	System	18 Aug 2020 02:24:47

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7dde1815-3a94-40c0-ab0c-d6acb5eb47ed' User entered 'No (N)'	System	18 Aug 2020 02:24:47
	System	18 Aug 2020 02:24:47

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7dde1815-3a94-40c0-ab0c-d6acb5eb47ed' User entered 'No (N)'	System	18 Aug 2020 02:24:47
	System	18 Aug 2020 02:24:47

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7dde1815-3a94-40c0-ab0c-d6acb5eb47ed' User entered 'None (1)'	System	18 Aug 2020 02:24:47
	System	18 Aug 2020 02:24:47

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7dde1815-3a94-40c0-ab0c-d6acb5eb47ed' User entered '17 Aug 2020 21:24'	System	18 Aug 2020 02:24:47
	System	18 Aug 2020 02:24:47

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 7'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '544b49bb-8f7c-4684-9117-cbc34f822caf'	System	18 Aug 2020 20:41:26
User entered 'None (1)'	System	18 Aug 2020 20:41:26

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '544b49bb-8f7c-4684-9117-cbc34f822caf' User entered 'No (N)'	System	18 Aug 2020 20:41:26
	System	18 Aug 2020 20:41:26

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '544b49bb-8f7c-4684-9117-cbc34f822caf' User entered 'No (N)'	System	18 Aug 2020 20:41:26
	System	18 Aug 2020 20:41:26

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '544b49bb-8f7c-4684-9117-cbc34f822caf' User entered 'None (1)'	System	18 Aug 2020 20:41:26
	System	18 Aug 2020 20:41:26

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:21', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '544b49bb-8f7c-4684-9117-cbc34f822caf' User entered '18 Aug 2020 15:41'	System	18 Aug 2020 20:41:26
	System	18 Aug 2020 20:41:26

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962' User entered 'None (0)'	System	12 Aug 2020 17:14:18
	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:54', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'None (0)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:13:58', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'None (0)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:14:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'None (0)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:14:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'None (0)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:14:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'None (0)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:14:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered 'No (N)'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T12:14:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '94904af0-874f-4530-bccb-bfc4ce7b9962'	System	12 Aug 2020 17:14:18
User entered '12 Aug 2020 12:14'	System	12 Aug 2020 17:14:18

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 14:29'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:47', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'None (0)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered 'No (N)'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-12T17:54:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ab3de159-448e-4579-a2e2-d506a433ae9a' User entered '12 Aug 2020 17:54'	System	12 Aug 2020 22:55:01
	System	12 Aug 2020 22:55:01

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '12 Aug 2020 15:24'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 2'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'None (0)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered 'No (N)'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-13T12:07:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ad38cdb8-fcbd-4f12-adf1-ecaa941254a2' User entered '13 Aug 2020 12:07'	System	13 Aug 2020 17:07:27
	System	13 Aug 2020 17:07:27

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 3'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:39:59', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:40:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:40:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:40:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2' User entered 'None (0)'	System	14 Aug 2020 22:40:15
	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:40:10', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2'	System	14 Aug 2020 22:40:15
User entered 'No (N)'	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-14T17:40:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd07f636e-35b6-45b7-918a-582c27399da2'	System	14 Aug 2020 22:40:15
User entered '14 Aug 2020 17:40'	System	14 Aug 2020 22:40:15

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 4'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:30', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'None (0)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered 'No (N)'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-15T17:31:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b146b29b-5ac0-4a4d-8864-3bd52221d57e' User entered '15 Aug 2020 17:31'	System	15 Aug 2020 22:31:55
	System	15 Aug 2020 22:31:55

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 5'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607' User entered 'None (0)'	System	16 Aug 2020 21:12:54
	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607'	System	16 Aug 2020 21:12:54
User entered 'None (0)'	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:38', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607' User entered 'None (0)'	System	16 Aug 2020 21:12:54
	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607' User entered 'None (0)'	System	16 Aug 2020 21:12:54
	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:43', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607' User entered 'None (0)'	System	16 Aug 2020 21:12:54
	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:46', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607' User entered 'None (0)'	System	16 Aug 2020 21:12:54
	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607'	System	16 Aug 2020 21:12:54
User entered 'No (N)'	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-16T16:12:52', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b7bfb689-5745-464b-9cb5-c05e07ba1607'	System	16 Aug 2020 21:12:54
User entered '16 Aug 2020 16:12'	System	16 Aug 2020 21:12:54

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 6'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:48', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:54', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:24:58', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'None (0)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:25:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered 'No (N)'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-17T21:25:07', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'eb5d6d9e-9fe2-435c-81b4-fe09e3786ac7' User entered '17 Aug 2020 21:25'	System	18 Aug 2020 02:25:08
	System	18 Aug 2020 02:25:08

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 7'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:27', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2'	System	18 Aug 2020 20:41:48
User entered 'No interference with activity (1)'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:31', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'None (0)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'None (0)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:35', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'None (0)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:37', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'None (0)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'None (0)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:41', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered 'No (N)'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-18T15:41:44', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6e1f6bbd-9678-4d4f-9aa8-5d6effd2a0f2' User entered '18 Aug 2020 15:41'	System	18 Aug 2020 20:41:48
	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Aug 2020 20:41:48
User entered 'Day 8'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Aug 2020 20:41:48
User entered 'Day 9'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-21T06:59:37', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f8bcd31-391f-44e7-959b-0122ed7548af'	System	21 Aug 2020 11:59:41
User entered 'No interference with activity (1)'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-21T06:59:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f8bcd31-391f-44e7-959b-0122ed7548af' User entered '21 Aug 2020 06:59'	System	21 Aug 2020 11:59:41
	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	21 Aug 2020 11:59:41
User entered 'Day 10'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	21 Aug 2020 11:59:41
User entered 'Day 11'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Aug 2020 20:41:48
User entered 'Day 8'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Aug 2020 20:41:48
User entered 'Day 9'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-21T06:59:46', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3637a08e-bf71-47c2-9edf-6ecc8d7d6245' User entered 'No (N)'	System	21 Aug 2020 11:59:54
	System	21 Aug 2020 11:59:54

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-08-21T06:59:52', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3637a08e-bf71-47c2-9edf-6ecc8d7d6245'	System	21 Aug 2020 11:59:54
User entered '21 Aug 2020 06:59'	System	21 Aug 2020 11:59:54

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:41:48

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	21 Aug 2020 11:59:41
User entered 'Day 10'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	21 Aug 2020 11:59:41
User entered 'Day 11'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

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)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 11:59:41

US3362116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 11:59:41

US3362116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:04:58

US3362116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:04:58

US3362116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:04:58

US3362116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:04:58

US3362116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:04:45

US3362116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	19 Aug 2020 16:04:45

US3362116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3362116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3362116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3362116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3362116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:33:16

US3362116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	28 Aug 2020 18:33:16

US3362116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:35:41

US3362116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:35:41

US3362116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:35:41

US3362116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:35:41

US3362116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:35:45

US3362116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	02 Sep 2020 17:35:45

US3362116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:48:57

US3362116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:35:32
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirmed as correct' (Site from System).	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:52:16
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Sep 2020 12:48:57
User entered '18 Sep 2020'	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:48:57

US3362116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Clinic (Clinic)'	Amy Thomassie (b) (4)	19 Sep 2020 12:48:57

US3362116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'VISIT2'	System	19 Sep 2020 12:48:57

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '10:49'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '18 Sep 2020 10:49'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '37.0' C	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Oral (Oral)'	(b) (4) Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '82'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'bpm'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '17'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'breaths/min'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '140'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '90'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	(b) (4) Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '12:11'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '18 Sep 2020 12:11'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '37.0' C	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Oral (Oral)'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '72'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'bpm'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'breaths/min'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '124'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '88'	Amy Thomassie (b) (4)	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	19 Sep 2020 12:51:04

US3362116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:46

US3362116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:46

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:40'	(b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '18 Sep 2020 11:40'	System	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'ONCE'	System	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 17:03:32

US3362116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:22

US3362116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:22

US3362116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:07'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:22

US3362116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '18 Sep 2020 11:07'	System	19 Sep 2020 12:49:22

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18 Sep 2020'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:06'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '18 Sep 2020 11:06'	System	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Thomassie (b) (4) (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	Amy Thomassie (b) (4)	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered empty.	System	19 Sep 2020 12:49:35

US3362116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Sep 2020 12:49:40

US3362116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'I'	System	19 Sep 2020 12:49:40

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:15:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'acccaa1e-751e-4384-a78a-91a6ef2a7197' User entered 'Yes (Y)'	System	18 Sep 2020 17:16:09
	System	18 Sep 2020 17:16:09

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:15:59', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'acccaa1e-751e-4384-a78a-91a6ef2a7197' User entered '98.5'	System	18 Sep 2020 17:16:09
	System	18 Sep 2020 17:16:09

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'acccaa1e-751e-4384-a78a-91a6ef2a7197'	System	18 Sep 2020 17:16:09
User entered 'No (N)'	System	18 Sep 2020 17:16:09

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'acccaa1e-751e-4384-a78a-91a6ef2a7197' User entered '18 Sep 2020 12:16'	System	18 Sep 2020 17:16:09
	System	18 Sep 2020 17:16:09

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 14:30'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29dd8e0d-eb68-4336-9e8b-412e7a161f88' User entered 'Yes (Y)'	System	19 Sep 2020 00:53:29
	System	19 Sep 2020 00:53:29

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29dd8e0d-eb68-4336-9e8b-412e7a161f88' User entered '97.5'	System	19 Sep 2020 00:53:29
	System	19 Sep 2020 00:53:29

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:23', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29dd8e0d-eb68-4336-9e8b-412e7a161f88'	System	19 Sep 2020 00:53:29
User entered 'No (N)'	System	19 Sep 2020 00:53:29

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:27', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29dd8e0d-eb68-4336-9e8b-412e7a161f88' User entered '18 Sep 2020 19:53'	System	19 Sep 2020 00:53:29
	System	19 Sep 2020 00:53:29

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 15:25'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 2'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40' User entered 'Yes (Y)'	System	19 Sep 2020 17:00:48
	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40' User entered '99.7'	System	19 Sep 2020 17:00:48
	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:26', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40'	System	19 Sep 2020 17:00:48
User entered 'Yes (Y)'	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PATIENT WAS CONTACTED ABOUT MEDICATION TAKEN. PATINET TOOK PREDNISONE. THIS IS LISTED IN CON MEDS.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:54:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 21:04:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40'	System	19 Sep 2020 17:00:48
User entered '1'	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40' User entered '0'	System	19 Sep 2020 17:00:48
	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:43', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'de021a98-5036-4e8b-9a51-56d9c8553c40' User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:00:48
	System	19 Sep 2020 17:00:48

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 3'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f' User entered 'Yes (Y)'	System	20 Sep 2020 19:02:39
	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f' User entered '96.7'	System	20 Sep 2020 19:02:39
	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:26', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f' User entered 'Yes (Y)'	System	20 Sep 2020 19:02:39
	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PATIENT WAS CONTACTED ABOUT MEDICATION TAKEN. PATINET TOOK PREDNISONE. THIS IS LISTED IN CON MEDS.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:54:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 21:04:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:34', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f'	System	20 Sep 2020 19:02:39
User entered '1'	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:34', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f' User entered '0'	System	20 Sep 2020 19:02:39
	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:37', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '085e114a-b67c-4f12-aa3f-7712cda5cc1f' User entered '20 Sep 2020 14:02'	System	20 Sep 2020 19:02:39
	System	20 Sep 2020 19:02:39

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 4'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd44082f2-655e-457b-a14a-f7d90a9c69ab' User entered 'Yes (Y)'	System	21 Sep 2020 18:24:22
	System	21 Sep 2020 18:24:22

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:10', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd44082f2-655e-457b-a14a-f7d90a9c69ab' User entered '96.6'	System	21 Sep 2020 18:24:22
	System	21 Sep 2020 18:24:22

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd44082f2-655e-457b-a14a-f7d90a9c69ab' User entered 'No (N)'	System	21 Sep 2020 18:24:22
	System	21 Sep 2020 18:24:22

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd44082f2-655e-457b-a14a-f7d90a9c69ab' User entered '21 Sep 2020 13:24'	System	21 Sep 2020 18:24:22
	System	21 Sep 2020 18:24:22

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 5'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '020f7158-1001-4a37-9c93-6badc4e4828b' User entered 'Yes (Y)'	System	22 Sep 2020 17:30:32
	System	22 Sep 2020 17:30:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:24', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '020f7158-1001-4a37-9c93-6badc4e4828b' User entered '96.9'	System	22 Sep 2020 17:30:32
	System	22 Sep 2020 17:30:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:27', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '020f7158-1001-4a37-9c93-6badc4e4828b' User entered 'No (N)'	System	22 Sep 2020 17:30:32
	System	22 Sep 2020 17:30:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:30', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '020f7158-1001-4a37-9c93-6badc4e4828b' User entered '22 Sep 2020 12:30'	System	22 Sep 2020 17:30:32
	System	22 Sep 2020 17:30:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 6'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:02:44', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '286bcf91-1af3-4cd5-8d78-f2e13305b4c1' User entered 'Yes (Y)'	System	23 Sep 2020 19:03:13
	System	23 Sep 2020 19:03:13

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:02:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '286bcf91-1af3-4cd5-8d78-f2e13305b4c1' User entered '97.7'	System	23 Sep 2020 19:03:13
	System	23 Sep 2020 19:03:13

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:02:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '286bcf91-1af3-4cd5-8d78-f2e13305b4c1' User entered 'No (N)'	System	23 Sep 2020 19:03:13
	System	23 Sep 2020 19:03:13

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '286bcf91-1af3-4cd5-8d78-f2e13305b4c1' User entered '23 Sep 2020 14:03'	System	23 Sep 2020 19:03:13
	System	23 Sep 2020 19:03:13

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 7'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:32', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1917f02c-0fb5-4c75-b711-2e14d7c2a590' User entered 'Yes (Y)'	System	24 Sep 2020 18:12:47
	System	24 Sep 2020 18:12:47

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1917f02c-0fb5-4c75-b711-2e14d7c2a590' User entered '98.6'	System	24 Sep 2020 18:12:47
	System	24 Sep 2020 18:12:47

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1917f02c-0fb5-4c75-b711-2e14d7c2a590' User entered 'No (N)'	System	24 Sep 2020 18:12:47
	System	24 Sep 2020 18:12:47

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1917f02c-0fb5-4c75-b711-2e14d7c2a590' User entered '24 Sep 2020 13:12'	System	24 Sep 2020 18:12:47
	System	24 Sep 2020 18:12:47

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:37', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7c78b6d0-f0d2-4493-9194-42a4841210f8' User entered 'None (1)'	System	18 Sep 2020 17:16:54
	System	18 Sep 2020 17:16:54

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7c78b6d0-f0d2-4493-9194-42a4841210f8' User entered 'No (N)'	System	18 Sep 2020 17:16:54
	System	18 Sep 2020 17:16:54

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7c78b6d0-f0d2-4493-9194-42a4841210f8' User entered 'No (N)'	System	18 Sep 2020 17:16:54
	System	18 Sep 2020 17:16:54

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:48', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7c78b6d0-f0d2-4493-9194-42a4841210f8' User entered 'None (1)'	System	18 Sep 2020 17:16:54
	System	18 Sep 2020 17:16:54

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7c78b6d0-f0d2-4493-9194-42a4841210f8' User entered '18 Sep 2020 12:16'	System	18 Sep 2020 17:16:54
	System	18 Sep 2020 17:16:54

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 14:30'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:35', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '954b1e8a-9930-4c4b-9df2-1ae6415c97d0'	System	19 Sep 2020 00:53:59
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 00:53:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:38', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '954b1e8a-9930-4c4b-9df2-1ae6415c97d0' User entered 'No (N)'	System	19 Sep 2020 00:53:59
	System	19 Sep 2020 00:53:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '954b1e8a-9930-4c4b-9df2-1ae6415c97d0' User entered 'No (N)'	System	19 Sep 2020 00:53:59
	System	19 Sep 2020 00:53:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '954b1e8a-9930-4c4b-9df2-1ae6415c97d0' User entered 'None (1)'	System	19 Sep 2020 00:53:59
	System	19 Sep 2020 00:53:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:53:58', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '954b1e8a-9930-4c4b-9df2-1ae6415c97d0' User entered '18 Sep 2020 19:53'	System	19 Sep 2020 00:53:59
	System	19 Sep 2020 00:53:59

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '18 Sep 2020 15:25'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 2'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:54', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '131820a3-1185-4d20-8675-0dbada7155aa'	System	19 Sep 2020 17:01:38
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:01:38

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:00:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '131820a3-1185-4d20-8675-0dbada7155aa' User entered 'No (N)'	System	19 Sep 2020 17:01:38
	System	19 Sep 2020 17:01:38

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '131820a3-1185-4d20-8675-0dbada7155aa' User entered 'No (N)'	System	19 Sep 2020 17:01:38
	System	19 Sep 2020 17:01:38

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '131820a3-1185-4d20-8675-0dbada7155aa'	System	19 Sep 2020 17:01:38
User entered 'None (1)'	System	19 Sep 2020 17:01:38

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '131820a3-1185-4d20-8675-0dbada7155aa' User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:01:38
	System	19 Sep 2020 17:01:38

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 3'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '06f77ab5-7291-476f-8343-62989b69e239'	System	20 Sep 2020 19:03:09
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 19:03:09

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '06f77ab5-7291-476f-8343-62989b69e239' User entered 'No (N)'	System	20 Sep 2020 19:03:09
	System	20 Sep 2020 19:03:09

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:02:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '06f77ab5-7291-476f-8343-62989b69e239' User entered 'No (N)'	System	20 Sep 2020 19:03:09
	System	20 Sep 2020 19:03:09

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '06f77ab5-7291-476f-8343-62989b69e239'	System	20 Sep 2020 19:03:09
User entered 'None (1)'	System	20 Sep 2020 19:03:09

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '06f77ab5-7291-476f-8343-62989b69e239' User entered '20 Sep 2020 14:03'	System	20 Sep 2020 19:03:09
	System	20 Sep 2020 19:03:09

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 4'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7bf8b977-9c39-49e0-b655-cb266e351cac' User entered 'None (1)'	System	21 Sep 2020 18:24:39
	System	21 Sep 2020 18:24:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:28', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7bf8b977-9c39-49e0-b655-cb266e351cac' User entered 'No (N)'	System	21 Sep 2020 18:24:39
	System	21 Sep 2020 18:24:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:30', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7bf8b977-9c39-49e0-b655-cb266e351cac' User entered 'No (N)'	System	21 Sep 2020 18:24:39
	System	21 Sep 2020 18:24:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:34', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7bf8b977-9c39-49e0-b655-cb266e351cac' User entered 'None (1)'	System	21 Sep 2020 18:24:39
	System	21 Sep 2020 18:24:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7bf8b977-9c39-49e0-b655-cb266e351cac'	System	21 Sep 2020 18:24:39
User entered '21 Sep 2020 13:24'	System	21 Sep 2020 18:24:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 5'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:34', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7797ddfd-e88c-4b2b-b468-f2d9996e4bdc' User entered 'None (1)'	System	22 Sep 2020 17:30:48
	System	22 Sep 2020 17:30:48

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:37', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7797ddfd-e88c-4b2b-b468-f2d9996e4bdc' User entered 'No (N)'	System	22 Sep 2020 17:30:48
	System	22 Sep 2020 17:30:48

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7797ddfd-e88c-4b2b-b468-f2d9996e4bdc' User entered 'No (N)'	System	22 Sep 2020 17:30:48
	System	22 Sep 2020 17:30:48

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7797ddfd-e88c-4b2b-b468-f2d9996e4bdc' User entered 'None (1)'	System	22 Sep 2020 17:30:48
	System	22 Sep 2020 17:30:48

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '7797ddfd-e88c-4b2b-b468-f2d9996e4bdc' User entered '22 Sep 2020 12:30'	System	22 Sep 2020 17:30:48
	System	22 Sep 2020 17:30:48

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 6'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:17', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '32092868-efa5-400b-9a9d-a09101299c54'	System	23 Sep 2020 19:03:39
User entered 'None (1)'	System	23 Sep 2020 19:03:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:21', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '32092868-efa5-400b-9a9d-a09101299c54'	System	23 Sep 2020 19:03:39
User entered 'No (N)'	System	23 Sep 2020 19:03:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:28', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '32092868-efa5-400b-9a9d-a09101299c54' User entered 'No (N)'	System	23 Sep 2020 19:03:39
	System	23 Sep 2020 19:03:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:32', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '32092868-efa5-400b-9a9d-a09101299c54' User entered 'None (1)'	System	23 Sep 2020 19:03:39
	System	23 Sep 2020 19:03:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '32092868-efa5-400b-9a9d-a09101299c54' User entered '23 Sep 2020 14:03'	System	23 Sep 2020 19:03:39
	System	23 Sep 2020 19:03:39

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 7'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'dbb9bdb3-7e98-4578-8d59-dfeb52f28763' User entered 'None (1)'	System	24 Sep 2020 18:13:03
	System	24 Sep 2020 18:13:03

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:52', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'dbb9bdb3-7e98-4578-8d59-dfeb52f28763' User entered 'No (N)'	System	24 Sep 2020 18:13:03
	System	24 Sep 2020 18:13:03

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:54', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'dbb9bdb3-7e98-4578-8d59-dfeb52f28763' User entered 'No (N)'	System	24 Sep 2020 18:13:03
	System	24 Sep 2020 18:13:03

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:12:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'dbb9bdb3-7e98-4578-8d59-dfeb52f28763' User entered 'None (1)'	System	24 Sep 2020 18:13:03
	System	24 Sep 2020 18:13:03

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'dbb9bdb3-7e98-4578-8d59-dfeb52f28763' User entered '24 Sep 2020 13:13'	System	24 Sep 2020 18:13:03
	System	24 Sep 2020 18:13:03

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:16:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'None (0)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered 'No (N)'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T12:17:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '0d6065bc-b77f-4ae6-bcd5-cdbd4e692b00' User entered '18 Sep 2020 12:17'	System	18 Sep 2020 17:17:22
	System	18 Sep 2020 17:17:22

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '18 Sep 2020 14:30'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'None (0)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:07', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8'	System	19 Sep 2020 00:54:41
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'None (0)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'None (0)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'None (0)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:20', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'None (0)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:35', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered 'No (N)'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-18T19:54:38', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9373c5dc-0a6a-4d85-a24c-0028618ca0c8' User entered '18 Sep 2020 19:54'	System	19 Sep 2020 00:54:41
	System	19 Sep 2020 00:54:41

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '18 Sep 2020 15:25'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 2'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:15:27
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'some interference with activity as no con med is reported ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 21:22:46
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:06:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:25', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87'	System	19 Sep 2020 17:02:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:33', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered 'Significant; prevents daily activity (3)'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:39', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered 'Some interference with activity (2)'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered 'Some interference with activity (2)'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:01:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered 'None (0)'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:02:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87'	System	19 Sep 2020 17:02:48
User entered 'Some interference with activity not requiring medical attention (2)'	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:02:13', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered 'No (N)'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-19T12:02:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9189081c-49fa-49a6-b06a-3d649063db87' User entered '19 Sep 2020 12:02'	System	19 Sep 2020 17:02:48
	System	19 Sep 2020 17:02:48

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 3'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:26', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95'	System	20 Sep 2020 19:04:17
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95'	System	20 Sep 2020 19:04:17
User entered 'Significant; prevents daily activity (3)'	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:47', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95'	System	20 Sep 2020 19:04:17
User entered 'Some interference with activity (2)'	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:03:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95'	System	20 Sep 2020 19:04:17
User entered 'Some interference with activity (2)'	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:04:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95' User entered 'None (0)'	System	20 Sep 2020 19:04:17
	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:04:08', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95'	System	20 Sep 2020 19:04:17
User entered 'No interference with activity (1)'	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:04:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95' User entered 'Yes (Y)'	System	20 Sep 2020 19:04:17
	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-20T14:04:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '3b86ca1a-29a5-46ab-8a81-08255c546b95' User entered '20 Sep 2020 14:04'	System	20 Sep 2020 19:04:17
	System	20 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 4'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'None (0)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:52', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75'	System	21 Sep 2020 18:25:19
User entered 'No interference with activity (1)'	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:24:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'None (0)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:25:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'None (0)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:25:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'None (0)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:25:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'None (0)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:25:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75' User entered 'No (N)'	System	21 Sep 2020 18:25:19
	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-21T13:25:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '52a1f285-7d0c-4572-99bf-58a278d06d75'	System	21 Sep 2020 18:25:19
User entered '21 Sep 2020 13:25'	System	21 Sep 2020 18:25:19

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 5'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06' User entered 'None (0)'	System	22 Sep 2020 17:31:09
	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06' User entered 'None (0)'	System	22 Sep 2020 17:31:09
	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06'	System	22 Sep 2020 17:31:09
User entered 'None (0)'	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06' User entered 'None (0)'	System	22 Sep 2020 17:31:09
	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:30:58', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06' User entered 'None (0)'	System	22 Sep 2020 17:31:09
	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:31:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06' User entered 'None (0)'	System	22 Sep 2020 17:31:09
	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:31:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06'	System	22 Sep 2020 17:31:09
User entered 'No (N)'	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-22T12:31:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'f3cc51c1-70f8-41e2-bdc2-e827ecee7c06'	System	22 Sep 2020 17:31:09
User entered '22 Sep 2020 12:31'	System	22 Sep 2020 17:31:09

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 6'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:42', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:44', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:03:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:04:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:04:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'None (0)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:04:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered 'No (N)'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-23T14:04:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e45d26da-60ad-4ae0-b024-8a1a79abf95e' User entered '23 Sep 2020 14:04'	System	23 Sep 2020 19:04:17
	System	23 Sep 2020 19:04:17

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
Data entry locked.	System	18 Sep 2020 17:03:32
User entered 'Day 7'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:08', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'None (0)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

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)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered 'No (N)'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-09-24T13:13:21', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'efb3b5f5-1760-4101-b6ed-c693d1b2f3a5' User entered '24 Sep 2020 13:13'	System	24 Sep 2020 18:13:23
	System	24 Sep 2020 18:13:23

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:03:32

US3362116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:33:12
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:03:32

US3362116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 21:23:03

US3362116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 21:23:03

US3362116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 21:23:03

US3362116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 21:23:03

US3362116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 21:23:09

US3362116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	25 Sep 2020 21:23:09

US3362116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 21:18:32

US3362116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 21:18:32

US3362116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:18:32

US3362116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 21:18:32

US3362116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 21:18:36

US3362116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	02 Oct 2020 21:18:36

US3362116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:59

US3362116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:59

US3362116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:59

US3362116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:23:59

US3362116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	09 Oct 2020 14:24:03

US3362116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:50:33

US3362116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:50:33

US3362116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:50:33

US3362116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'VISIT3'	System	14 Oct 2020 20:50:33

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:21'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '14 Oct 2020 11:21'	System	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '84'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'bpm'	System	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '18'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'breaths/min'	System	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '122'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '90'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'mmHg'	System	14 Oct 2020 20:51:49

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58

US3362116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58

US3362116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:57

US3362116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:51:57

US3362116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:52:12

US3362116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:52:12

US3362116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered '11:31'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:52:12

US3362116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered '14 Oct 2020 11:31'	System	14 Oct 2020 20:52:12

US3362116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 14:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:52:15

US3362116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:58
User entered 'I'	System	14 Oct 2020 20:52:15

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 64'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-12T00:06:55', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9a73442c-db2d-4041-9697-e804c71eaac5' User entered 'No (N)'	System	12 Oct 2020 05:07:15
	System	12 Oct 2020 05:07:15

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with 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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-12T00:07:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9a73442c-db2d-4041-9697-e804c71eaac5'	System	12 Oct 2020 05:07:15
User entered 'No (N)'	System	12 Oct 2020 05:07:15

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-12T00:07:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '9a73442c-db2d-4041-9697-e804c71eaac5' User entered '12 Oct 2020 00:07:12'	System	12 Oct 2020 05:07:15
	System	12 Oct 2020 05:07:15

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 71'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-19T22:01:07', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '4d155abb-0d0c-4492-9bbf-5926db168311' User entered 'No (N)'	System	20 Oct 2020 03:01:21
	System	20 Oct 2020 03:01:21

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with 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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-19T22:01:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '4d155abb-0d0c-4492-9bbf-5926db168311' User entered 'No (N)'	System	20 Oct 2020 03:01:21
	System	20 Oct 2020 03:01:21

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-19T22:01:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '4d155abb-0d0c-4492-9bbf-5926db168311' User entered '19 Oct 2020 22:01:19'	System	20 Oct 2020 03:01:21
	System	20 Oct 2020 03:01:21

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 78'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-26T08:00:40', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56f728b0-a63e-4653-8e0d-cdd7505cc931' User entered 'No (N)'	System	26 Oct 2020 13:00:53
	System	26 Oct 2020 13:00:53

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with 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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-26T08:00:46', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56f728b0-a63e-4653-8e0d-cdd7505cc931'	System	26 Oct 2020 13:00:53
User entered 'No (N)'	System	26 Oct 2020 13:00:53

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-10-26T08:00:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56f728b0-a63e-4653-8e0d-cdd7505cc931' User entered '26 Oct 2020 08:00:49'	System	26 Oct 2020 13:00:53
	System	26 Oct 2020 13:00:53

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 92'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-09T05:18:02', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce6f5a1f-4426-47c9-85c7-f66e9ae8fcd2'	System	09 Nov 2020 11:18:16
User entered 'No (N)'	System	09 Nov 2020 11:18:16

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with 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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-09T05:18:07', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce6f5a1f-4426-47c9-85c7-f66e9ae8fcd2'	System	09 Nov 2020 11:18:16
User entered 'No (N)'	System	09 Nov 2020 11:18:16

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-09T05:18:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce6f5a1f-4426-47c9-85c7-f66e9ae8fcd2' User entered '09 Nov 2020 05:18:15'	System	09 Nov 2020 11:18:16
	System	09 Nov 2020 11:18:16

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered 'Day 99'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-16T06:38:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '22f99e78-a421-4e50-8e37-e647ae2d3f67'	System	16 Nov 2020 12:38:23
User entered 'No (N)'	System	16 Nov 2020 12:38:23

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with 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 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-16T06:38:17', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '22f99e78-a421-4e50-8e37-e647ae2d3f67'	System	16 Nov 2020 12:38:23
User entered 'No (N)'	System	16 Nov 2020 12:38:23

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-16T06:38:21', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '22f99e78-a421-4e50-8e37-e647ae2d3f67' User entered '16 Nov 2020 06:38:21'	System	16 Nov 2020 12:38:23
	System	16 Nov 2020 12:38:23

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 16:41:36

US3362116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:28:21
Data entry locked.	System	12 Aug 2020 16:41:36
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 16:41:36

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-23T07:42:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd0969cde-47bc-4089-b163-8d6743f0d661' User entered 'No (N)'	System	23 Nov 2020 13:43:08

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-23T07:43:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd0969cde-47bc-4089-b163-8d6743f0d661'	System	23 Nov 2020 13:43:08
User entered 'No (N)'	System	23 Nov 2020 13:43:08

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-23T07:43:03', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'd0969cde-47bc-4089-b163-8d6743f0d661' User entered '23 Nov 2020 07:43:03'	System	23 Nov 2020 13:43:08
	System	23 Nov 2020 13:43:08

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-29T12:01:50', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1b02a58d-f4c6-41b9-992a-de8f4a6b5291'	System	29 Nov 2020 18:01:59
User entered 'No (N)'	System	29 Nov 2020 18:01:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-29T12:01:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1b02a58d-f4c6-41b9-992a-de8f4a6b5291'	System	29 Nov 2020 18:01:59
User entered 'No (N)'	System	29 Nov 2020 18:01:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-11-29T12:01:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '1b02a58d-f4c6-41b9-992a-de8f4a6b5291' User entered '29 Nov 2020 12:01:57'	System	29 Nov 2020 18:01:59
	System	29 Nov 2020 18:01:59

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-04T11:54:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a9078ee8-7209-453e-af29-b63bb0ea9c45'	System	04 Dec 2020 17:55:12
User entered 'No (N)'	System	04 Dec 2020 17:55:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-04T11:55:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a9078ee8-7209-453e-af29-b63bb0ea9c45'	System	04 Dec 2020 17:55:12
User entered 'No (N)'	System	04 Dec 2020 17:55:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-04T11:55:08', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'a9078ee8-7209-453e-af29-b63bb0ea9c45' User entered '04 Dec 2020 11:55:08'	System	04 Dec 2020 17:55:12
	System	04 Dec 2020 17:55:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-11T00:01:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '755d5fbc-ae80-468e-93bb-bc277e26ff73'	System	11 Dec 2020 06:02:11
User entered 'No (N)'	System	11 Dec 2020 06:02:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-11T00:02:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '755d5fbc-ae80-468e-93bb-bc277e26ff73'	System	11 Dec 2020 06:02:11
User entered 'No (N)'	System	11 Dec 2020 06:02:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-11T00:02:06', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '755d5fbc-ae80-468e-93bb-bc277e26ff73' User entered '11 Dec 2020 00:02:06'	System	11 Dec 2020 06:02:11
	System	11 Dec 2020 06:02:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-20T12:43:38', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '85fa6a88-da70-455d-8f9a-bb16670030f4'	System	20 Dec 2020 18:43:47
User entered 'No (N)'	System	20 Dec 2020 18:43:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-20T12:43:41', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '85fa6a88-da70-455d-8f9a-bb16670030f4'	System	20 Dec 2020 18:43:47
User entered 'No (N)'	System	20 Dec 2020 18:43:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-20T12:43:44', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '85fa6a88-da70-455d-8f9a-bb16670030f4' User entered '20 Dec 2020 12:43:44'	System	20 Dec 2020 18:43:47
	System	20 Dec 2020 18:43:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-25T00:01:56', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04cf877d-c67b-4587-9b91-52a60a676524' User entered 'No (N)'	System	25 Dec 2020 06:02:12
	System	25 Dec 2020 06:02:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-25T00:02:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04cf877d-c67b-4587-9b91-52a60a676524' User entered 'No (N)'	System	25 Dec 2020 06:02:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2020-12-25T00:02:08', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '04cf877d-c67b-4587-9b91-52a60a676524' User entered '25 Dec 2020 00:02:08'	System	25 Dec 2020 06:02:12
	System	25 Dec 2020 06:02:12

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-01T00:08:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '309877df-40bd-4266-a3a3-fb4e6bc5577e' User entered 'No (N)'	System	01 Jan 2021 06:09:11
	System	01 Jan 2021 06:09:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-01T00:09:05', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '309877df-40bd-4266-a3a3-fb4e6bc5577e' User entered 'No (N)'	System	01 Jan 2021 06:09:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-01T00:09:09', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '309877df-40bd-4266-a3a3-fb4e6bc5577e' User entered '01 Jan 2021 00:09:09'	System	01 Jan 2021 06:09:11
	System	01 Jan 2021 06:09:11

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:38', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced' User entered 'Yes (Y)'	System	08 Jan 2021 06:43:09
	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:41', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced' User entered 'No (N)'	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced' User entered 'No (N)'	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:51', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced' User entered 'Yes (Y)'	System	08 Jan 2021 06:43:09
	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:54', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced'	System	08 Jan 2021 06:43:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-08T00:42:59', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '807d7a43-2d54-4e90-9a90-a58ffa205ced' User entered '08 Jan 2021 00:42:59'	System	08 Jan 2021 06:43:09
	System	08 Jan 2021 06:43:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-15T00:07:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '91ea697f-cdce-4b33-9ebc-2fb1b41ee641' User entered 'Yes (Y)'	System	15 Jan 2021 06:07:47
	System	15 Jan 2021 06:07:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-15T00:07:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '91ea697f-cdce-4b33-9ebc-2fb1b41ee641'	System	15 Jan 2021 06:07:47
User entered 'No (N)'	System	15 Jan 2021 06:07:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-15T00:07:16', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '91ea697f-cdce-4b33-9ebc-2fb1b41ee641' User entered 'No (N)'	System	15 Jan 2021 06:07:47
	System	15 Jan 2021 06:07:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-15T00:07:36', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '91ea697f-cdce-4b33-9ebc-2fb1b41ee641'	System	15 Jan 2021 06:07:47
User entered 'No (N)'	System	15 Jan 2021 06:07:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-15T00:07:46', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '91ea697f-cdce-4b33-9ebc-2fb1b41ee641' User entered '15 Jan 2021 00:07:46'	System	15 Jan 2021 06:07:47
	System	15 Jan 2021 06:07:47

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:09:12', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994'	System	22 Jan 2021 06:10:43
User entered 'Yes (Y)'	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:09:18', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994'	System	22 Jan 2021 06:10:43
User entered 'No (N)'	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:09:22', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994'	System	22 Jan 2021 06:10:43
User entered 'No (N)'	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:09:45', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994'	System	22 Jan 2021 06:10:43
User entered 'Yes (Y)'	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:10:28', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994'	System	22 Jan 2021 06:10:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-22T00:10:32', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'b3e05e09-3f34-4153-a9cc-72754220b994' User entered '22 Jan 2021 00:10:32'	System	22 Jan 2021 06:10:43
	System	22 Jan 2021 06:10:43

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:15', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b' User entered 'Yes (Y)'	System	31 Jan 2021 18:09:55
	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:23', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b' User entered 'No (N)'	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:27', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b' User entered 'No (N)'	System	31 Jan 2021 18:09:55
	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:35', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b' User entered 'Yes (Y)'	System	31 Jan 2021 18:09:55
	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:41', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b'	System	31 Jan 2021 18:09:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-01-31T12:09:47', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '96e438c3-b017-4bb6-b490-dca32de9a98b' User entered '31 Jan 2021 12:09:47'	System	31 Jan 2021 18:09:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-05T00:40:49', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cbf7aae8-7611-4785-842e-fa742ffc487e' User entered 'No (N)'	System	05 Feb 2021 06:41:00
	System	05 Feb 2021 06:41:00

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-05T00:40:53', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cbf7aae8-7611-4785-842e-fa742ffc487e'	System	05 Feb 2021 06:41:00
User entered 'No (N)'	System	05 Feb 2021 06:41:00

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-05T00:40:57', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cbf7aae8-7611-4785-842e-fa742ffc487e' User entered '05 Feb 2021 00:40:57'	System	05 Feb 2021 06:41:00
	System	05 Feb 2021 06:41:00

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-14T12:03:01', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '488c5792-3827-4459-9b45-254eb5bd935d' User entered 'No (N)'	System	14 Feb 2021 18:05:52
	System	14 Feb 2021 18:05:52

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-14T12:03:04', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '488c5792-3827-4459-9b45-254eb5bd935d'	System	14 Feb 2021 18:05:52
User entered 'No (N)'	System	14 Feb 2021 18:05:52

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-14T12:03:08', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '488c5792-3827-4459-9b45-254eb5bd935d'	System	14 Feb 2021 18:05:52
User entered '14 Feb 2021 12:03:08'	System	14 Feb 2021 18:05:52

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-19T00:04:11', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '61c9935e-cbd9-471c-8bc6-af061add0638' User entered 'No (N)'	System	19 Feb 2021 06:04:22
	System	19 Feb 2021 06:04:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-19T00:04:14', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '61c9935e-cbd9-471c-8bc6-af061add0638' User entered 'No (N)'	System	19 Feb 2021 06:04:22
	System	19 Feb 2021 06:04:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-19T00:04:19', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '61c9935e-cbd9-471c-8bc6-af061add0638' User entered '19 Feb 2021 00:04:19'	System	19 Feb 2021 06:04:22
	System	19 Feb 2021 06:04:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-26T01:25:54-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b37a783-bd59-4300-a123-62f50d708629'	System	26 Feb 2021 07:26:03
User entered 'No (N)'	System	26 Feb 2021 07:26:03

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-26T01:25:57-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b37a783-bd59-4300-a123-62f50d708629'	System	26 Feb 2021 07:26:03
User entered 'No (N)'	System	26 Feb 2021 07:26:03

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-02-26T01:26:01-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '6b37a783-bd59-4300-a123-62f50d708629'	System	26 Feb 2021 07:26:03
User entered '26 Feb 2021 07:26:01'	System	26 Feb 2021 07:26:03

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-05T00:08:53-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56853a91-0640-4bc3-97da-7d0fe22d8609'	System	05 Mar 2021 06:09:15
User entered 'No (N)'	System	05 Mar 2021 06:09:15

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-05T00:08:56-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56853a91-0640-4bc3-97da-7d0fe22d8609'	System	05 Mar 2021 06:09:15
User entered 'No (N)'	System	05 Mar 2021 06:09:15

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-05T00:09:01-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '56853a91-0640-4bc3-97da-7d0fe22d8609' User entered '05 Mar 2021 00:09:01'	System	05 Mar 2021 06:09:15
	System	05 Mar 2021 06:09:15

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-12T00:03:58-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce12e390-43c6-4c3c-b18b-fe92e37f2bdc'	System	12 Mar 2021 06:04:09
User entered 'No (N)'	System	12 Mar 2021 06:04:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-12T00:04:02-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce12e390-43c6-4c3c-b18b-fe92e37f2bdc'	System	12 Mar 2021 06:04:09
User entered 'No (N)'	System	12 Mar 2021 06:04:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-12T00:04:05-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ce12e390-43c6-4c3c-b18b-fe92e37f2bdc'	System	12 Mar 2021 06:04:09
User entered '12 Mar 2021 00:04:05'	System	12 Mar 2021 06:04:09

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-19T04:51:11-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29ea092a-c2b2-42b7-838f-fad460183cfa' User entered 'No (N)'	System	19 Mar 2021 09:51:28
	System	19 Mar 2021 09:51:28

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-19T04:51:20-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29ea092a-c2b2-42b7-838f-fad460183cfa'	System	19 Mar 2021 09:51:28
User entered 'No (N)'	System	19 Mar 2021 09:51:28

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-19T04:51:25-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '29ea092a-c2b2-42b7-838f-fad460183cfa' User entered '19 Mar 2021 04:51:25'	System	19 Mar 2021 09:51:28
	System	19 Mar 2021 09:51:28

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-28T12:07:35-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'fd47152e-a44f-427a-ab37-5f9bdba269af' User entered 'No (N)'	System	28 Mar 2021 17:08:58
	System	28 Mar 2021 17:08:58

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-28T12:07:39-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'fd47152e-a44f-427a-ab37-5f9bdba269af' User entered 'No (N)'	System	28 Mar 2021 17:08:58
	System	28 Mar 2021 17:08:58

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-28T12:07:42-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'fd47152e-a44f-427a-ab37-5f9bdba269af' User entered '28 Mar 2021 12:07:42'	System	28 Mar 2021 17:08:58
	System	28 Mar 2021 17:08:58

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-05T17:59:13-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ef739d22-daae-4430-b80c-3991406a1254'	System	05 Apr 2021 22:59:22
User entered 'No (N)'	System	05 Apr 2021 22:59:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-05T17:59:15-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ef739d22-daae-4430-b80c-3991406a1254'	System	05 Apr 2021 22:59:22
User entered 'No (N)'	System	05 Apr 2021 22:59:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-05T17:59:18-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'ef739d22-daae-4430-b80c-3991406a1254'	System	05 Apr 2021 22:59:22
User entered '05 Apr 2021 17:59:18'	System	05 Apr 2021 22:59:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-13T11:59:22-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e4d94f16-16ff-4160-843e-21948827ee51'	System	13 Apr 2021 16:59:31
User entered 'No (N)'	System	13 Apr 2021 16:59:31

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-13T11:59:26-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e4d94f16-16ff-4160-843e-21948827ee51'	System	13 Apr 2021 16:59:31
User entered 'No (N)'	System	13 Apr 2021 16:59:31

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-13T11:59:28-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e4d94f16-16ff-4160-843e-21948827ee51'	System	13 Apr 2021 16:59:31
User entered '13 Apr 2021 11:59:28'	System	13 Apr 2021 16:59:31

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-16T10:11:23-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '664ddff8-46e9-4b7e-a797-e961dc07dde7' User entered 'No (N)'	System	16 Apr 2021 15:11:36
	System	16 Apr 2021 15:11:36

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-16T10:11:26-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '664ddff8-46e9-4b7e-a797-e961dc07dde7'	System	16 Apr 2021 15:11:36
User entered 'No (N)'	System	16 Apr 2021 15:11:36

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-16T10:11:30-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '664ddff8-46e9-4b7e-a797-e961dc07dde7'	System	16 Apr 2021 15:11:36
User entered '16 Apr 2021 10:11:30'	System	16 Apr 2021 15:11:36

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-23T06:25:32-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cfd2bf3e-0902-4de5-a732-cc0f934133ec' User entered 'No (N)'	System	23 Apr 2021 11:25:42

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-23T06:25:36-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cfd2bf3e-0902-4de5-a732-cc0f934133ec' User entered 'No (N)'	System	23 Apr 2021 11:25:42

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-04-23T06:25:40-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'cfd2bf3e-0902-4de5-a732-cc0f934133ec' User entered '23 Apr 2021 06:25:40'	System	23 Apr 2021 11:25:42
	System	23 Apr 2021 11:25:42

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-05-02T12:02:16-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e3a68607-dd5f-41b9-a4be-94f031dbb04c'	System	02 May 2021 17:05:55
User entered 'No (N)'	System	02 May 2021 17:05:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-05-02T12:02:24-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e3a68607-dd5f-41b9-a4be-94f031dbb04c'	System	02 May 2021 17:05:55
User entered 'No (N)'	System	02 May 2021 17:05:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-05-02T12:02:34-05:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: 'e3a68607-dd5f-41b9-a4be-94f031dbb04c'	System	02 May 2021 17:05:55
User entered '02 May 2021 12:02:34'	System	02 May 2021 17:05:55

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 04:53:22

US3362116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:22
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 04:53:22

US3362116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-05T00:09:08-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '16132958-3c0d-4698-9ea9-1e70f51120de'	System	05 Mar 2021 06:09:17
User entered 'No (N)'	System	05 Mar 2021 06:09:17

US3362116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:22

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:20:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04ED6801-5D47-43BC-A705-2CEAE6AE8162)', Time: '2021-03-05T00:09:13-06:00', User OID: 'PatientReportedOutcome (US3362116)', ODM File OID: '16132958-3c0d-4698-9ea9-1e70f51120de' User entered '05 Mar 2021 00:09:13'	System	05 Mar 2021 06:09:17
	System	05 Mar 2021 06:09:17

US3362116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:22
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Dec 2020 17:21:50

US3362116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:22
User entered '10 Nov 2020'	Alexandra Caillouet (b) (4)	14 Dec 2020 17:21:50

US3362116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:22
User entered 'Contact Made (CONTACT MADE)'	Alexandra Caillouet (b) (4)	14 Dec 2020 17:21:50

US3362116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:22
User entered empty.	Alexandra Caillouet (b) (4)	14 Dec 2020 17:21:50

US3362116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:20:22
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Dec 2020 17:21:55

US3362116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:28:55
User entered 'I'	System	14 Dec 2020 17:21:55

US3362116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:01:37

US3362116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:01:37

US3362116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:01:37

US3362116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:01:37

US3362116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:00

US3362116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User entered 'I'	System	14 Jan 2021 15:36:00

US3362116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:11

US3362116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:11

US3362116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:11

US3362116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:11

US3362116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:36:16

US3362116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User entered 'I'	System	14 Jan 2021 15:36:16

US3362116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:49:11

US3362116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	15 Feb 2021 21:49:17
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Feb 2021 21:49:17
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:49:17
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Feb 2021 21:49:11
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Feb 2021 21:49:11

US3362116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Feb 2021 21:49:11

US3362116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:49:11

US3362116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:49:21

US3362116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:43:34
User entered 'I'	System	15 Feb 2021 21:49:21

US3362116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:33:30

US3362116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:33:30

US3362116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:33:30

US3362116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered 'VISIT4'	System	03 Mar 2021 22:33:30

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered empty.	System	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered empty.	System	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered empty.	System	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered empty.	System	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered empty.	System	30 Mar 2021 18:42:24

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37

US3362116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37

US3362116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:34:48

US3362116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	Alexandra Caillouet (b) (4)	03 Mar 2021 22:34:48

US3362116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:35:13

US3362116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:35:13

US3362116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '09:09'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:35:13

US3362116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered '3 Mar 2021 09:09'	System	03 Mar 2021 22:35:13

US3362116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 22:35:18

US3362116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:37
User entered 'I'	System	03 Mar 2021 22:35:18

US3362116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:25:29

US3362116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:25:29

US3362116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:25:29

US3362116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:25:29

US3362116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:25:34

US3362116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 15:25:34

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:04

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '27 Jan 2021'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:04

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:04

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 20:56:04

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '27 Jan 2021'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:20:59

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:20:59

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '27 Jan 2021'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User entered empty.	System	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:16:22

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User entered empty.	System	27 Jan 2021 20:57:07

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:28

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '27 Jan 2021'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:28

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '09:08'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:28

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User entered '27 Jan 2021 09:08'	System	27 Jan 2021 20:56:28

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:40

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '27 Jan 2021'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:40

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '09:13'	Alexandra Caillouet (b) (4)	27 Jan 2021 20:56:40

US3362116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:22

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:42
User entered '27 Jan 2021 09:13'	System	27 Jan 2021 20:56:40

US3362116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:16:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:20
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary, Headache lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:39:43
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary, Headache lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'AE will be added.' (Site from DM).	Alexandra Caillouet (b) (4)	19 Apr 2021 19:46:07
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 diary, Headache lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 02:56:50
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:13:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 12:51:08
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:18:05

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Low back strain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 11:23:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 11:23:42
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Back strain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 12:58:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 12:58:37
	(b) (4)	
Data point term sent to Coder System	System	05 Sep 2020 12:57:55
User entered 'lower back muscle strain'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '31 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User entered empty.	System	05 Sep 2020 12:57:21

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:30:54
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	27 Nov 2020 17:08:53
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	27 Nov 2020 17:08:43
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:28:27
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '11 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet	27 Nov 2020 17:08:43
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User entered empty.	System	05 Sep 2020 12:57:21

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'I'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alexandra Caillouet	27 Nov 2020 17:08:43
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:57:21
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User entered '0'	System	05 Sep 2020 12:57:21

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09
User entered '1'	System	05 Sep 2020 12:57:21

US3362116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:09

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 14:49:15
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'PD documented ' (Site from DM).	Crystal Rowell (b) (4)	31 Dec 2020 17:23:39
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:45:39
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 16:12:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 16:12:51
Data point term sent to Coder	System	01 Dec 2020 16:11:43
Coding entries removed.	(b) (4), (b) (6)	01 Dec 2020 16:11:19
User entered 'Sore Throat (PHARYNGITIS)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 16:11:19

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:10:57
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'symptoms did not last more than 48 hours; subject was not scheduled for illness ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:06:46
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:18:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:30:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:30:55
Data point term sent to Coder	System	30 Sep 2020 16:29:42
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:29:04
User entered 'pharyngitis' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:29:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:35:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:35:35
Data point term sent to Coder	System	06 Sep 2020 15:35:12
User entered 'sore throat'	Amy Thomassie (b) (4) (b) (4)	06 Sep 2020 15:34:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

1751 of 2294

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '15 Aug 2020'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User entered empty.	System	06 Sep 2020 15:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Alexandra Caillouet	02 Dec 2020 14:39:44
	(b) (4)	
User entered '15 Aug 2020'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User entered empty.	System	06 Sep 2020 15:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	09 Oct 2020 16:55:33
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Crystal Rowell (b) (4)	30 Sep 2020 16:28:55
	(b) (4)	
' answered with 'updated ' (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	22 Sep 2020 02:14:47
' (Site from DM).		
User entered 'I'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	06 Sep 2020 15:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User entered '0'	System	06 Sep 2020 15:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34
User entered '0'	System	06 Sep 2020 15:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:34

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:32:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:32:50
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:31:47
User entered 'chills'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:41:00
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	25 Nov 2020 19:12:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	25 Nov 2020 19:12:51
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:48:57
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:31:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:31:10
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 16:31:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:31:01
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '19 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '04:30'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User entered '19 Sep 2020 04:30'	System	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '20 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '10:00'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User entered '20 Sep 2020 10:00'	System	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:25:03
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per CDM(DM CLR Re-Query): Response noted, However Start date of corresponding CM is not reflecting in AE. Please verify and update. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:39:27
Query 'Per CDM(DM CLR Re-Query): Response noted, However Start date of corresponding CM is not reflecting in AE. Please verify and update. Thank you.' answered with 'No medication taken for "Chills"' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:25:17
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:25:03
User opened query 'Per CDM(DM CLR Re-Query): Response noted, However Start date of corresponding CM is not reflecting in AE. Please verify and update. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:08:01
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	04 Nov 2020 11:08:01
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Amy Thomassie (b) (4)	31 Oct 2020 13:12:45
' answered with 'conmed #7' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	30 Oct 2020 03:35:18
' (Site from DM).		

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:31:01
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User entered '0'	System	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59
User entered '1'	System	30 Sep 2020 16:31:01

US3362116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:59

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MYALGIA. 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) (4), (b) (6)	04 Nov 2020 11:09:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 13:14:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 13:14:28
Data point term sent to Coder	System	31 Oct 2020 13:13:28
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MYALGIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	31 Oct 2020 13:13:19
Coding entries removed.	Amy Thomassie (b) (4) (b) (4)	31 Oct 2020 13:13:11
User entered 'generalized MYALGIAS' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	31 Oct 2020 13:13:11
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MYALGIA. 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)	30 Oct 2020 03:35:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:34:47

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Sep 2020 16:34:47
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:33:51
User entered 'myalgias'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:41:17
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	25 Nov 2020 19:13:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	25 Nov 2020 19:13:22
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Medically-attended AE; Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:49:07
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:33:12

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:33:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:33:18
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 16:33:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:33:12
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '19 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '04:30'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User entered '19 Sep 2020 04:30'	System	30 Sep 2020 16:33:12

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '21 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '08:00'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User entered '21 Sep 2020 08:00'	System	30 Sep 2020 16:33:12

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	12 Jan 2021 21:32:25
reason for change: Data Entry Error	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Jan 2021 21:34:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	13 Jan 2021 16:45:03
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Amy Thomassie (b) (4)	12 Jan 2021 21:34:47
	(b) (4)	
' answered with 'corrected to none. ' (Site from DM).		
User entered '0' reason for change: Data Entry Error	Amy Thomassie (b) (4)	12 Jan 2021 21:34:30
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	11 Jan 2021 05:08:03
' (Site from DM).		
User entered '1'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:33:12
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User entered '0'	System	30 Sep 2020 16:33:12

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23
User entered '1'	System	30 Sep 2020 16:33:12

US3362116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:23

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per MM: Only one term should be used. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 05:12:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 11:27:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 11:27:49
Data point term sent to Coder	System	29 Oct 2020 19:04:33
Query 'Per MM: Only one term should be used. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:03:50
Coding entries removed.		29 Oct 2020 19:03:44
User entered 'WORSENING OF CHRONIC NECK PAIN' reason for change: Data Entry Error		29 Oct 2020 19:03:44
User opened query 'Per MM: Only one term should be used. ' (Site from DM).		22 Oct 2020 18:27:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:43:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:43:01
Data point term sent to Coder	System	30 Sep 2020 16:34:53
User entered 'Acute Neck pain (worsening of chronic neck pain)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:34:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:34:59
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 16:34:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:34:52
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '19 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '04:30'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User entered '19 Sep 2020 04:30'	System	30 Sep 2020 16:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '21 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '08:00'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User entered '21 Sep 2020 08:00'	System	30 Sep 2020 16:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'I'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:34:52
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User entered '0'	System	30 Sep 2020 16:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44
User entered '1'	System	30 Sep 2020 16:34:52

US3362116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:44

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:40:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:40:16
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:36:55
User entered 'headache'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:36:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:36:39
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 16:36:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:36:19
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '19 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '04:30'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User entered '19 Sep 2020 04:30'	System	30 Sep 2020 16:36:19

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '21 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:36:39
User entered '08:00' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Sep 2020 16:36:39
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:36:19
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User entered '21 Sep 2020 08:00'	System	30 Sep 2020 16:36:39
User entered empty.	System	30 Sep 2020 16:36:19

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Related (RELATED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'None (NONE)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'I'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:36:19
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User entered '0'	System	30 Sep 2020 16:36:19

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06
User entered '1'	System	30 Sep 2020 16:36:19

US3362116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:18:06

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
Reviewed for Safety.	(b) (4)	03 Mar 2021 15:54:27
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:53:12
Reviewed for Safety.		03 Mar 2021 15:53:04
User entered empty.		11 Jan 2021 01:24:38

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Ear infection, LLT: Ear infection - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 15:09:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 15:09:40
	(b) (4)	
Data point term sent to Coder	System	08 Jan 2021 15:09:08
User entered 'Ear infection'	(b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:08:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:08:48
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'Updated' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 01:24:34
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Jan 2021 23:15:01
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 17:19:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Per CDM: According to CCGs 'Not applicable' is used when the clinical event occurred prior to administration of IP. Kindly review and update as needed, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:18:58
Query 'Per CDM: According to CCGs 'Not applicable' is used when the clinical event occurred prior to administration of IP. Kindly review and update as needed, else provide clarification. ' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	12 Jan 2021 21:30:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Jan 2021 21:29:53
User opened query 'Per CDM: According to CCGs 'Not applicable' is used when the clinical event occurred prior to administration of IP. Kindly review and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 21:12:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	12 Jan 2021 21:30:15
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 15:08:48

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
Reviewed for Safety.	(b) (4)	03 Mar 2021 15:53:18
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:53:12
Reviewed for Safety.		03 Mar 2021 15:52:58
Un-reviewed for Safety.		03 Mar 2021 15:52:54
Reviewed for Safety.		17 Feb 2021 14:53:23
User entered 'USA-US112-2021-mRNA-1273-P301000009'	System	17 Feb 2021 14:53:15
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 14:53:15

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 15:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:00:45
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of abdominal wall - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:20:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:20:03
Data point term sent to Coder	System	02 Mar 2021 23:18:29
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 23:17:32
User entered 'CELLULITIS OF LEFT ABDOMEN' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 23:17:32
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial infection, LLT: Bacterial infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:31:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:31:00
Data point term sent to Coder	System	16 Feb 2021 23:20:34
User entered 'BACTERIAL INFECTION OF LEFT ABDOMEN'	(b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
	(b) (4)	
User entered '08 Feb 2021' reason for change: Data Entry Error	Alexandra Caillouet	04 Mar 2021 21:11:52
	(b) (4)	
User entered '02 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	16 Feb 2021 23:24:53
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		16 Feb 2021 23:24:53
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Feb 2021 23:24:53
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	16 Feb 2021 23:20:33
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:13:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:53:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:53:38
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)	03 Mar 2021 15:53:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'NO RELEVANT LABORATORY RESULTS' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:17:44
User entered 'PER PATIENT, PATIENT WENT FOR ROUTINE HERNIA REPAIR ON 21JAN2021. PATIENT DEVELOPED BACTERIAL INFECTION OF LEFT ABDOMEN AS COMPLICATION FROM PROCEDURE. PATIENT WAS HOSPITALIZED AND TREATED FOR A STAPHYLOCOCCUS INFECTION. PATIENT WAS DISCHARGED ON 02FEB2021. MEDICAL RECORDS REQUESTED. SAE ENTERED IN EDC.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 23:17:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

1999 of 2294

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con meds updated' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:16:34
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 'COVID-19 Test was not done .' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:16:20
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:11:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:11:33
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)	25 Feb 2021 15:11:15
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Feb 2021 23:37:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Feb 2021 23:37:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Per patient, patient went for routine hernia repair on 30JAN2021. Patient developed Bacterial Infection of left abdomen as complication from procedure. Patient was hospitalized and treated for a Staphylococcus Infection. Patient was discharged on 02FEB2021. Medical Records requested. SAE entered in EDC.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 23:37:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Feb 2021 23:20:33
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 23:20:33

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:58:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:58:40
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 21:57:37
User entered 'headache'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '15 Aug 2020'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User entered empty.	System	19 Apr 2021 21:57:08

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '22 Aug 2020'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User entered empty.	System	19 Apr 2021 21:57:08

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 16:15:23
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 16:15:23
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'None (NONE)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'I'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered '0'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User signature succeeded.	Jordan Whatley (b) (4)	20 Apr 2021 00:57:51
	(b) (4)	
User entered empty.	Alexandra Caillouet	19 Apr 2021 21:57:08
	(b) (4)	

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User entered '0'	System	19 Apr 2021 21:57:08

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31
User entered '0'	System	19 Apr 2021 21:57:08

US3362116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:16:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:15:31

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:16:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:18:24

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 11:10:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:10:31
Data point term sent to Coder	System	12 Aug 2020 20:20:09
User entered 'Tramadol'	(b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Chronic Neck Pain'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '50'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 11:53:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication ongoing at IP injection.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 20:21:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:19:28
User entered 'UN UNK 2018'	(b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:19:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 20:22:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:22:10
Data point term sent to Coder	System	12 Aug 2020 20:21:10
User entered 'ATORVASTATIN'	(b) (4), (b) (6) (b) (4)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '20'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 11:53:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication ongoing at IP injection.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 20:20:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:20:35
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 20:20:35
User entered 'UN Dec 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:20:35
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 20:20:22
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:20:22

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:24:10
Data point term sent to Coder	System	12 Aug 2020 20:23:16
User entered 'Aspirin'	(b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Coronary Artery Disease'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '81'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 11:54:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication ongoing at IP injection. ' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 20:22:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:22:25
User entered 'UN Dec 2016'	(b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:22:25

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 12:48:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 12:48:36
Data point term sent to Coder	System	05 Sep 2020 12:47:49
User entered 'Tylenol'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Headache'	(b) (4) Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '500'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'three times daily (TID)'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '15 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '15 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES; however Headache = None on 15AUG2020 in eDiary Please review and update if this should be recorded as AE. If yes, please update response to "No". Otherwise, please provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:55:49
Query 'Per DM CLR: Was this medication taken for solicited event? = YES; however Headache = None on 15AUG2020 in eDiary Please review and update if this should be recorded as AE. If yes, please update response to "No". Otherwise, please provide clarification.' answered with 'day 9 on diary has headache listed' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:27:38
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES; however Headache = None on 15AUG2020 in eDiary Please review and update if this should be recorded as AE. If yes, please update response to "No". Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:52:17
Query 'Per DM CLR: Was this medication taken for solicited event? = YES; however Headache = None on 15AUG2020 in eDiary Please review and update if this should be changed to "No". Otherwise, please provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:52:09
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES; however Headache = None on 15AUG2020 in eDiary Please review and update if this should be changed to "No". Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:51:14
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User entered '3'	System	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User entered '1'	System	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:30
User entered '804 (804)'	System	05 Sep 2020 12:47:44

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:16:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:16:44
Data point term sent to Coder	System	05 Sep 2020 12:50:50
User entered 'mobic'	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Sep 2020 12:50:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 12:50:44
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 12:50:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Sep 2020 12:50:28
User entered empty.	System	05 Sep 2020 12:50:28
	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'lower back muscle strain'	(b) (4) Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '15'	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4)	
	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	(b) (4)	
	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4)	
	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4)	
	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '31 Aug 2020'	(b) (4) Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:30:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated query per chart documentation' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 23:54:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 23:53:46
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:07:32
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 23:53:46
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 12:57:54
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User entered '1'	System	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User entered '1'	System	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:37
User entered '804 (804)'	System	05 Sep 2020 12:50:28

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:52:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:52:52
Data point term sent to Coder	System	30 Sep 2020 16:27:37
User entered 'azithromycin'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per CDM-CLR RQ: Please review if Start and Stop dates of corresponding AE entered correctly as per records, If it is correct please clarify why CM was continued to use even after AE resolved on 15AUG2020.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 08:49:22
Query 'Per CDM-CLR RQ: Please review if Start and Stop dates of corresponding AE entered correctly as per records, If it is correct please clarify why CM was continued to use even after AE resolved on 15AUG2020.' answered with 'updated AE' (Site from DM).	Alexandra Caillouet (b) (4)	02 Dec 2020 14:40:26
User opened query 'Per CDM-CLR RQ: Please review if Start and Stop dates of corresponding AE entered correctly as per records, If it is correct please clarify why CM was continued to use even after AE resolved on 15AUG2020.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:41:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:41:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Hi, there is an AE reported during Aug 15. Please let me know if there is additional information needed. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:12:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:13:05
User entered 'pharyngitis'	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:27:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

2134 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '500'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '17 Aug 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '21 Aug 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User entered '1'	System	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User entered '1'	System	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:42
User entered '804 (804)'	System	30 Sep 2020 16:27:13

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 04:08:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 04:08:34
Data point term sent to Coder Coding entries removed.	System Alexandra Caillouet	05 Apr 2021 21:39:14 05 Apr 2021 21:38:52
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 08:23:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 08:23:39
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:11:54
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Nov 2020 16:26:37 04 Nov 2020 16:25:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Nov 2020 04:55:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Nov 2020 04:55:41
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'end date updated. medication taken for 10 days' (Site from DM).	Amy Thomassie (b) (4)	31 Oct 2020 13:11:58
Data point term sent to Coder	System	31 Oct 2020 13:11:27
Coding entries removed.	Amy Thomassie (b) (4)	31 Oct 2020 13:10:52
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:05:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Oct 2020 07:17:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Oct 2020 07:17:40
Data point term sent to Coder	System	30 Sep 2020 16:28:41
User entered 'prednisone'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

2151 of 2294

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:59:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Indication updated to match MAAE of worsening of chronic neck pain' (Site from DM).	Alexandra Caillouet (b) (4)	05 Apr 2021 21:40:40
User entered 'Worsening of chronic neck pain and generalized myalgias.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	05 Apr 2021 21:38:52

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:20:02
User entered 'HEADACHE/NECKPAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:25:43
User entered 'HEADACHE/NECKPAIN/MYALGIAS/chills' reason for change: Data Entry Error	Amy Thomassie (b) (4)	31 Oct 2020 13:10:52
User entered 'headache/neckpain/myalgias'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '20'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '20 Sep 2020'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amy Thomassie (b) (4)	31 Oct 2020 13:11:34
User entered 'Yes (Y)'	(b) (4)	
	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27
	(b) (4)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '21 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	05 Apr 2021 21:38:52
User entered '22 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	05 Apr 2021 21:36:09
User entered '30 Sep 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	31 Oct 2020 13:11:34
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 05:42:22
Query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'per query resolved' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:14:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 16:14:25
User opened query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:14:32
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:28:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:28:32
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:28:32
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:28:27
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User entered '1'	System	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User entered '1'	System	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:51
User entered '804 (804)'	System	30 Sep 2020 16:28:27

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 15:13:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:13:40
Data point term sent to Coder	System	08 Jan 2021 15:11:10
Data point term sent to Coder	System	08 Jan 2021 15:10:09
User entered 'Ciprofloxacin'	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'ear infection'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered '500' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	08 Jan 2021 15:10:28
User entered '5 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:16:26
Query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	14 Jan 2021 18:33:12
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 18:33:07
User opened query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:20:52
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:10:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 15:10:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 15:10:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 15:09:59
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 15:10:28
User entered empty.	System	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 15:10:28
User entered empty.	System	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 15:10:28
User entered empty.	System	08 Jan 2021 15:09:59

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent)..' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent)..' answered with 'medication was prescribed 5 months after meeting eligibility criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:50
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent)..' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	01 Feb 2021 12:18:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4)	01 Feb 2021 10:39:07 08 Jan 2021 15:12:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:12:40
Data point term sent to Coder	System	08 Jan 2021 15:12:10
User entered 'Prednisone'	(b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'ear infection'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '20'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:16:35
Query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	14 Jan 2021 18:33:29
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 18:33:24
User opened query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:21:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 15:11:23

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 23:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 23:17:49
Data point term sent to Coder	System	02 Mar 2021 23:16:27
User entered 'BACTRIM DS'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'CELLULITIS OF LEFT ABDOOMEN'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:53:44
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Amy Thomassie (b) (4) (b) (4)	12 Mar 2021 21:12:25
' answered with 'updated ' (Site from DM).		
User entered '800/160' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	12 Mar 2021 21:06:48
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	12 Mar 2021 10:40:50
' (Site from DM).		
User entered '1'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:06:48
User entered 'Other (OTHER)'	Amy Thomassie (b) (4)	02 Mar 2021 23:15:43
	(b) (4), (b) (6)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty; reason for change Data Entry Error	(b) (4)	12 Mar 2021 21:06:48
User entered 'TABLET'	Amy Thomassie (b) (4)	02 Mar 2021 23:15:43
	(b) (4), (b) (6)	

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User entered '2'	System	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User entered '1'	System	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:09:58
User entered '804 (804)'	System	02 Mar 2021 23:15:43

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:16:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	16 Feb 2021 23:21:18
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:18:14

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:59:09
User entered '30 Jan 2021'	(b) (4), (b) (6)	16 Feb 2021 23:21:42

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered 'Hernia Repair'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:21:42

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:03:15
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'will update med history ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 21:20:36
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:11:18
User entered 'Medical History (MH)'	(b) (4), (b) (6)	16 Feb 2021 23:21:42

US3362116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:22

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:51:08
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 23:21:42

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'USA-US112-2021-MRNA-1273-P301000009'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Jordan'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Whatley'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '5326 O'donovan dr'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'baton rouge'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '70808'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'US'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 15:19:50
User entered '2'	System	03 Mar 2021 15:55:03
User entered '1'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'USA-US112-2021-MRNA-1273-P301000009'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Jordan'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Whatley'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '5326 O'donovan dr'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'baton rouge'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '70808'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'US'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 15:19:50
User entered '2'	System	03 Mar 2021 15:55:03
User entered '1'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '17/Feb/2021 14:54'	(b) (4) System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'USA-US112-2021-MRNA-1273-P301000009'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Jordan'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Whatley'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '5326 O'donovan dr'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'baton rouge'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '70808'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'US'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 15:19:50
User entered '2'	System	03 Mar 2021 15:55:03
User entered '1'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '03/Mar/2021 10:54'	(b) (4) System	03 Mar 2021 15:55:03

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 15:55:03

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'USA-US112-2021-MRNA-1273-P301000009'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Yes (Y)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'No (N)'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Jordan'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'Whatley'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '5326 O'donovan dr'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered 'baton rouge'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:54:42
User entered '70808'	System	17 Feb 2021 14:53:15

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:36
User entered 'US'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 15:19:50
User entered '2'	System	03 Mar 2021 15:55:03
User entered '1'	System	17 Feb 2021 14:54:51

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered '05/Mar/2021 09:19'	(b) (4) System	05 Mar 2021 15:19:50

US3362116

Folder: SAE USA-US112-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:14:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:50