

US3372229 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:39:46

All time stamps listed in this document are displayed in GMT

US3372229

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:44:43

Generated On: 11 Aug 2021 22:39:46

[Participant ID](#)

US3372229

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

US3372229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:14:18

Generated On: 11 Aug 2021 22:39:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3372229

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:08:10

Generated On: 11 Aug 2021 22:39:46

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3372229

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:23:36

Generated On: 11 Aug 2021 22:39:46

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 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

US3372229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:20:25

Generated On: 11 Aug 2021 22:39:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3372229

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:52:40

Generated On: 11 Aug 2021 22:39:46

Were any significant conditions reported?

Yes ☒
No ☐

US3372229

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372229

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	22 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	22 NOV 2017
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	NOV 2017
Stop Year (derived)	2017

US3372229

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

Condition	MYOPIA (NEAR SIGHTED)
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3372229

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

Condition	MACROMASTIA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3372229

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:36:30

Generated On: 11 Aug 2021 22:39:46

Condition	BILATERAL REDUCTION MAMMOPLASTY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3372229

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:30:45

Generated On: 11 Aug 2021 22:39:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:12
Height (xxx.x)	168.6 cm
Weight (xxx.x)	78 kg
BMI (xxx.x)	27.43971 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372229

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:08:24

Generated On: 11 Aug 2021 22:39:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3372229

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 18:00:39

Generated On: 11 Aug 2021 22:39:46

Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3372229

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 01:23:16

Generated On: 11 Aug 2021 22:39:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3372229

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:18:45

Generated On: 11 Aug 2021 22:39:46

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 VETERINARIAN

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3372229

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:18:45

Generated On: 11 Aug 2021 22:39:46

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	

US3372229

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:14:18

Generated On: 11 Aug 2021 22:39:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 02:01:57

Generated On: 11 Aug 2021 22:39:46

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

What was the participant's randomization number? 144609

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 ☒

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:47:03

Generated On: 11 Aug 2021 22:39:46

Height	ND - Not Done
Weight	ND - Not Done

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:47:03

Generated On: 11 Aug 2021 22:39:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:12
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:47:03

Generated On: 11 Aug 2021 22:39:46

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)	24 AUG 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:01
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372229

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:08:24

Generated On: 11 Aug 2021 22:39:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 14 Apr 2021 15:54:13

Generated On: 11 Aug 2021 22:39:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:44:38

Generated On: 11 Aug 2021 22:39:46

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:19 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 15:19

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

US3372229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:04:11

Generated On: 11 Aug 2021 22:39:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

14:33 (24 HR)

Collection date and time (derived)

24 AUG 2020 14:33

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:19:43

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:31	24 AUG 2020 14:31
Nasopharyngeal Swab 2	No		

US3372229

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 16:00

PC Open Date & Time

24 AUG 2020 15:39

PC Close Date & Time

24 AUG 2020 18:09

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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	24 AUG 2020 20:05
PC Open Date & Time	24 AUG 2020 19:04
PC Close Date & Time	25 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

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

26 AUG 2020 07:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 07:39

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

27 AUG 2020 18:49

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

28 AUG 2020 21:24

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

29 AUG 2020 20:45

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 20:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 16:03

PC Open Date & Time

24 AUG 2020 15:39

PC Close Date & Time

24 AUG 2020 18:09

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:06

PC Open Date & Time

24 AUG 2020 19:04

PC Close Date & Time

25 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

26 AUG 2020 00:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 18:50

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

28 AUG 2020 21:25

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

29 AUG 2020 20:45

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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 ☐

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 16:04
PC Open Date & Time	24 AUG 2020 15:39
PC Close Date & Time	24 AUG 2020 18:09

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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 ☐

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:06
PC Open Date & Time	24 AUG 2020 19:04
PC Close Date & Time	25 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 00:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 07:39
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:50
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:25
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 20:46
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

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 ☒

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:20
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3372229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

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)	28 SEP 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:05
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3372229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3372229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:21:32

Generated On: 11 Aug 2021 22:39:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

13:32 (24 HR)

Collection date and time (derived)

28 SEP 2020 13:32

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:19:43

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:31	28 SEP 2020 13:31
Nasopharyngeal Swab 2	No		

US3372229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 19:23:57

Generated On: 11 Aug 2021 22:39:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 11 Aug 2021 22:39:46

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) _____

US3372229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 11 Aug 2021 22:39:46

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.

US3372229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:02:05

Generated On: 11 Aug 2021 22:39:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	13:01 (24 HR)
Collection date and time (derived)	19 OCT 2020 13:01

US3372229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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	24 OCT 2020 00:49:40
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 OCT 2020 09:37:52
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 07:10:36

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 17:04:59
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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="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"/>

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 08:23:53

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 06:55:23
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 06:29:14

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3372229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:36:01

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:24:32

Generated On: 11 Aug 2021 22:39:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:24:32

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3372229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3372229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

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.

US3372229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3372229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Apr 2021 19:07:35

Generated On: 11 Aug 2021 22:39:46

Date of Contact	14 JAN 2021
Time of Contact	10:17
Date and Time of Contact (derived)	14 JAN 2021 10:17
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

133 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

137 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

141 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

145 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

149 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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153 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

157 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Symptom Day

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

161 of 1890

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 13:20:59

Generated On: 11 Aug 2021 22:39:46

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Date of Visit	14 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	14 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 JAN 2021
Day 5	Yes	18 JAN 2021
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3372229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:20
Height (xxx.x)	167.6 cm
Weight (xxx.x)	87.5 kg
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3372229

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3372229

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:14:18

Generated On: 11 Aug 2021 22:39:46

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
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US3372229

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

Form: Unblinding

Data signed: (b) (4) 19 Apr 2021 19:07:35

Generated On: 11 Aug 2021 22:39:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3372229

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Height	ND - Not Done
Weight	ND - Not Done

US3372229

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

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

US3372229

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

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

US3372229

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:08:24

Generated On: 11 Aug 2021 22:39:46

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.

US3372229

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 20:52:24

Generated On: 11 Aug 2021 22:39:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

08:39 (24 HR)

Collection date and time (derived)

27 JAN 2021 08:39

US3372229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Feb 2021 20:52:24

Generated On: 11 Aug 2021 22:39:46

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)	08:37
Collection Date and Time (derived)	27 JAN 2021 08:37

US3372229

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:07

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 15:54:13

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 15:54:13

Generated On: 11 Aug 2021 22:39:46

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

OLD29 Placebo Flag

US3372229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:46:41

Generated On: 11 Aug 2021 22:39:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID

Adverse event

HYPEREMESIS

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)

30 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

UN FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

184 of 1890

EAB) (1725)

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID	
Adverse event	DEHYDRATION
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

186 of 1890

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID

Adverse event

PREGNANCY

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)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

188 of 1890

EAB) (1725)

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID

Adverse event

SORE THROAT

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)

12 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)

17 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

190 of 1890

EAB) (1725)

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 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)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

192 of 1890

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID

Adverse event

NASAL CONGESTIONS

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)

12 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)

18 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

194 of 1890

EAB) (1725)

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

AEID	
Adverse event	RHINORRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 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)	18 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

196 of 1890

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 16:38:30

Generated On: 11 Aug 2021 22:39:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:46:13

Generated On: 11 Aug 2021 22:39:46

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

Yes ☒

No ☐

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

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

199 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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 SEP 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2018
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication DIPHTHERIA PERTUSSIS
VACCINE

Prophylaxis Yes ☒
No ☐

Indication DIPHTHERIA/TETANUS AND
ACELLULAR PERTUSSIS
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

201 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	UN	UNK 2017
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication JAPANESE ENCEPHALITIS
VACCINE

Prophylaxis Yes ☒
No ☐

Indication JAPANESE ENCEPHALITIS
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

203 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2013
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"/>

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication RABIES VACCINE

Prophylaxis Yes ☒
No ☐

Indication RABIES PROPHYLACTIC

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

205 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2013		
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"/>

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

207 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	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 FEB 2019	
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"/>

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication HYPEREMESIS

Dose per administration 8

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

209 of 1890

EAB) (1725)

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

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

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

Name of Medication MRNA 1237 VACCINE

Prophylaxis Yes ☒
No ☐

Indication COVID-19 PREVENTION /
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

211 of 1890

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 15:54:12

Generated On: 11 Aug 2021 22:39:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	14 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)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:11:36

Generated On: 11 Aug 2021 22:39:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3372229

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 21:54:02

Generated On: 11 Aug 2021 22:39:46

Date of dosing discontinuation (dd MMM yyyy) 28 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 30 Apr 2021 13:45:39

Generated On: 11 Aug 2021 22:39:46

Date of study discontinuation/completion (dd MMM yyyy) 01 MAR 2021

Reason for discontinuation

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

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

SUBJECT IS PREGNANT AND DID NOT WANT TO CONTINUE WITH THE STUDY. CONSENT WAS WITHDRAWN.

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

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

Audit

US3372229 (Prod: Palm Beach Research Center)

US3372229

Form: Participant Creation

Generated On: 11 Aug 2021 22:39:46

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 23:50:53
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:44:43
User entered 'US3372229'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:29:47

US3372229

Form: Participant Creation

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:48:49

US3372229

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:30
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:29:48

US3372229

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[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 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 19:48:49

US3372229

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'SCRN'	System	24 Aug 2020 19:48:49

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:29:49

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:30:45
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'demographics form has been completed' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:09:06
User entered '34'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 07:12:46

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'YEARS'	System	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '34'	System	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered 'Female (F)'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered 'I'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered empty.	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:46

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:36:48
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 21:08:47

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Aug 2020'	System	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2020'	System	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:50:10

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:29:48

US3372229

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'I'	System	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:20:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:39:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:52:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:37:27
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:17:09

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:21:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:21:56
Data point term sent to Coder	System	01 Sep 2020 15:20:48
User entered 'depression'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2004'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2004'	System	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2004'	System	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered empty.	System	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered empty.	System	01 Sep 2020 15:20:42

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:22:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:22:46
Data point term sent to Coder	System	01 Sep 2020 15:21:49
User entered 'cesarean section'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '22 Nov 2017'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '22 Nov 2017'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Nov 2017'	System	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2017'	System	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Nov 2017'	System	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2017'	System	01 Sep 2020 15:21:01

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:52:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:52:45
Data point term sent to Coder	System	01 Sep 2020 15:21:49
User entered 'myopia (near sighted)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 1995'	System	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '1995'	System	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2009'	System	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2009'	System	01 Sep 2020 15:21:24

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Photorefractive keratectomy, LLT: Photorefractive keratectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:59:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:59:32
Data point term sent to Coder	System	01 Sep 2020 15:22:52
User entered 'bilateral photorefractive keratectomy'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2009'	System	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2009'	System	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2009'	System	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2009'	System	01 Sep 2020 15:21:51

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Breast enlargement, LLT: Macromastia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:23:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:23:48
Data point term sent to Coder	System	01 Sep 2020 15:22:53
User entered 'macromastia'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2002'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2002'	System	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2002'	System	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2005'	System	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2005'	System	01 Sep 2020 15:22:09

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:30:52
Data point term sent to Coder	System	01 Sep 2020 15:30:12
User entered 'bilateral reduction mammoplasty'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:19
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2005'	System	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2005'	System	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'Jan 2005'	System	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '2005'	System	01 Sep 2020 15:30:03

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '14:12'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 14:12'	System	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '168.6' cm	Peter Jacob (b) (4)	01 Sep 2020 15:39:00
DataPoint set to visible.	(b) (4) System	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '78' kg	Peter Jacob (b) (4)	01 Sep 2020 15:39:00
DataPoint set to visible.	(b) (4) System	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '27.43971'	System	01 Sep 2020 15:39:00
DataPoint set to visible.	System	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'kg/m2'	System	01 Sep 2020 15:39:00
DataPoint set to visible.	System	24 Aug 2020 19:50:19

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:09:02
DataPoint Un-verified.	Peter Jacob (b) (4)	06 Oct 2020 17:15:50
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 05:34:16
	(b) (4), (b) (6)	
User entered '36.9' C	Peter Jacob (b) (4)	04 Sep 2020 12:38:37
	(b) (4)	
	Peter Jacob (b) (4)	01 Sep 2020 15:39:00
	(b) (4)	

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User entered empty; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '60'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'bpm'	System	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '14'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'breaths/min'	System	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '101'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:30:45
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:38:37
User entered '68'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:39:00

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31

US3372229

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31

US3372229

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:55
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:10

US3372229

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:38:55
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:10

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:00:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:07
User entered '0'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:21

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered 'Urine (URINE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered 'Negative (NEGATIVE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:22
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered empty.	System	01 Sep 2020 15:39:31

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'Veterinarian'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered 'l'	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:36
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:51:45

US3372229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:49:04

US3372229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:57
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 19:49:04

US3372229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[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 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:39:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 19:49:04

US3372229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'VISIT1'	System	24 Aug 2020 19:49:04

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:49:35

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered '144609'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:49:35

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:44:06
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'error made in endpoint' (Site from System).	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 18:27:32
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:06:56
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	System	30 Sep 2020 21:06:56
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:06
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:08:47
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:49:35

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

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 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:49:34

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

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 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:49:34

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:49:34

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:49:34

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:06
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:49:34

US3372229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:01:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 18:27:25
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:40:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:41:45

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:40:01
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:48
answered with 'data updated' (Site from DM).		
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:34:08
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '168.9' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '78' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:40:01
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:48
answered with 'data updated' (Site from DM).		
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:34:08
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '168.9' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '78' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '14:12'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 14:12'	System	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '36.9' C	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '60'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'bpm'	System	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '14'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'breaths/min'	System	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '101'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '68'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 07:40:01
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:48
answered with 'data updated' (Site from DM).		
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 17:15:24
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:34:08
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '168.9' cm	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:15:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 17:15:24
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '78' kg	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:44:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed.	(b) (4)	17 Sep 2020 21:50:50
' canceled (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed.	(b) (4), (b) (6)	09 Sep 2020 22:01:06
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '16:01'	Peter Jacob (b) (4)	01 Sep 2020 15:57:53
	(b) (4)	

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 16:01'	System	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '37.1' C	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '66'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'bpm'	System	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '16'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'breaths/min'	System	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '106'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:40:30
User entered '74'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'mmHg'	System	01 Sep 2020 15:57:53

US3372229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:41:41
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:58:52

US3372229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:41:41
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:58:52

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User closed query 'Please complete this page, thanks. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:10:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
Query 'Please complete this page, thanks. ' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:41:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 17:40:46
User opened query 'Please complete this page, thanks. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:29:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered '24 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'Urine (URINE)'	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:10:34
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered empty.	System	13 Apr 2021 17:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 12:28:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Sep 2020 12:42:03

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
Query 'According to eMR patient did not received the 2nd dose due to AE (pregnancy). Please review and reconcile or clarify. Thanks, (b) (6). ' canceled (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:25:16
User opened query 'According to eMR patient did not received the 2nd dose due to AE (pregnancy). Please review and reconcile or clarify. Thanks, (b) (6). ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:25:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered '15:19'	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 15:19'	System	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:44:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 12:42:11
User entered 'ONCE'	System	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 19:52:18

US3372229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:32
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:59:55

US3372229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:32
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:59:55

US3372229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:32
User entered '14:33'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 15:59:55

US3372229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 14:33'	System	01 Sep 2020 15:59:55

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:42
User entered '24 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:42
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:42
User entered '14:31'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '24 Aug 2020 14:31'	System	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:42
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:42
User entered empty.	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered empty.	System	01 Sep 2020 16:04:26

US3372229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:42:52
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Sep 2020 16:05:10

US3372229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered '1'	System	01 Sep 2020 16:05:10

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T15:59:38', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0bc4953d-5a5a-488e-8310-65f1b1a95e58'	System	24 Aug 2020 20:00:10
User entered 'Yes (Y)'	System	24 Aug 2020 20:00:10

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T15:59:51', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0bc4953d-5a5a-488e-8310-65f1b1a95e58'	System	24 Aug 2020 20:00:10
User entered '98.8'	System	24 Aug 2020 20:00:10

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T15:59:59', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0bc4953d-5a5a-488e-8310-65f1b1a95e58'	System	24 Aug 2020 20:00:10
User entered 'No (N)'	System	24 Aug 2020 20:00:10

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:00:06', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0bc4953d-5a5a-488e-8310-65f1b1a95e58'	System	24 Aug 2020 20:00:10
User entered '24 Aug 2020 16:00'	System	24 Aug 2020 20:00:10

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 15:39'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:09'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:03:37', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '93ee9ade-aaf3-4da6-ba05-c3c0e6c12a8c'	System	25 Aug 2020 00:05:06
User entered 'Yes (Y)'	System	25 Aug 2020 00:05:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:04:58', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '93ee9ade-aaf3-4da6-ba05-c3c0e6c12a8c'	System	25 Aug 2020 00:05:06
User entered '98.2'	System	25 Aug 2020 00:05:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:05:01', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '93ee9ade-aaf3-4da6-ba05-c3c0e6c12a8c'	System	25 Aug 2020 00:05:06
User entered 'No (N)'	System	25 Aug 2020 00:05:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:05:05', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '93ee9ade-aaf3-4da6-ba05-c3c0e6c12a8c'	System	25 Aug 2020 00:05:06
User entered '24 Aug 2020 20:05'	System	25 Aug 2020 00:05:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:04'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 2'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T07:31:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8d875482-86c7-4a63-977f-00f7d40b9c9b'	System	26 Aug 2020 11:31:58
User entered 'Yes (Y)'	System	26 Aug 2020 11:31:58

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T07:31:44', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8d875482-86c7-4a63-977f-00f7d40b9c9b'	System	26 Aug 2020 11:31:58
User entered '96.6'	System	26 Aug 2020 11:31:58

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T07:31:47', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8d875482-86c7-4a63-977f-00f7d40b9c9b'	System	26 Aug 2020 11:31:58
User entered 'No (N)'	System	26 Aug 2020 11:31:58

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T07:31:55', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8d875482-86c7-4a63-977f-00f7d40b9c9b'	System	26 Aug 2020 11:31:58
User entered '26 Aug 2020 07:31'	System	26 Aug 2020 11:31:58

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 3'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:38:56', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '137c28cb-c409-481e-9331-efb62d015b78'	System	27 Aug 2020 11:39:06
User entered 'Yes (Y)'	System	27 Aug 2020 11:39:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:38:59', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '137c28cb-c409-481e-9331-efb62d015b78'	System	27 Aug 2020 11:39:06
User entered '98.4'	System	27 Aug 2020 11:39:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:01', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '137c28cb-c409-481e-9331-efb62d015b78'	System	27 Aug 2020 11:39:06
User entered 'No (N)'	System	27 Aug 2020 11:39:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:03', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '137c28cb-c409-481e-9331-efb62d015b78'	System	27 Aug 2020 11:39:06
User entered '27 Aug 2020 07:39'	System	27 Aug 2020 11:39:06

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 4'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:29', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '89943ee2-63fc-4a06-8905-94431a2ce8f1'	System	27 Aug 2020 22:49:41
User entered 'Yes (Y)'	System	27 Aug 2020 22:49:41

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:33', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '89943ee2-63fc-4a06-8905-94431a2ce8f1' User entered '98.2'	System	27 Aug 2020 22:49:41
	System	27 Aug 2020 22:49:41

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:37', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '89943ee2-63fc-4a06-8905-94431a2ce8f1'	System	27 Aug 2020 22:49:41
User entered 'No (N)'	System	27 Aug 2020 22:49:41

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '89943ee2-63fc-4a06-8905-94431a2ce8f1'	System	27 Aug 2020 22:49:41
User entered '27 Aug 2020 18:49'	System	27 Aug 2020 22:49:41

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 5'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:24:31', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f5be2602-57f0-4995-87da-f6718d9ad764'	System	29 Aug 2020 01:24:48
User entered 'Yes (Y)'	System	29 Aug 2020 01:24:48

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:24:36', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f5be2602-57f0-4995-87da-f6718d9ad764'	System	29 Aug 2020 01:24:48
User entered '97.5'	System	29 Aug 2020 01:24:48

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:24:39', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f5be2602-57f0-4995-87da-f6718d9ad764'	System	29 Aug 2020 01:24:48
User entered 'No (N)'	System	29 Aug 2020 01:24:48

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:24:41', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f5be2602-57f0-4995-87da-f6718d9ad764'	System	29 Aug 2020 01:24:48
User entered '28 Aug 2020 21:24'	System	29 Aug 2020 01:24:48

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 6'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:23', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0af0839c-d1db-481f-9fd9-ca91ae915f3a'	System	30 Aug 2020 00:45:39
User entered 'Yes (Y)'	System	30 Aug 2020 00:45:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:27', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0af0839c-d1db-481f-9fd9-ca91ae915f3a'	System	30 Aug 2020 00:45:39
User entered '96.8'	System	30 Aug 2020 00:45:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:30', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0af0839c-d1db-481f-9fd9-ca91ae915f3a'	System	30 Aug 2020 00:45:39
User entered 'No (N)'	System	30 Aug 2020 00:45:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0af0839c-d1db-481f-9fd9-ca91ae915f3a'	System	30 Aug 2020 00:45:39
User entered '29 Aug 2020 20:45'	System	30 Aug 2020 00:45:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 7'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:28', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9b5a001d-e8d7-4a35-8dbc-01387d661b3f'	System	31 Aug 2020 00:19:39
User entered 'Yes (Y)'	System	31 Aug 2020 00:19:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9b5a001d-e8d7-4a35-8dbc-01387d661b3f' User entered '97.7'	System	31 Aug 2020 00:19:39
	System	31 Aug 2020 00:19:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:34', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9b5a001d-e8d7-4a35-8dbc-01387d661b3f'	System	31 Aug 2020 00:19:39
User entered 'No (N)'	System	31 Aug 2020 00:19:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:37', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9b5a001d-e8d7-4a35-8dbc-01387d661b3f'	System	31 Aug 2020 00:19:39
User entered '30 Aug 2020 20:19'	System	31 Aug 2020 00:19:39

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:02:23', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0d730ab1-a81e-431f-bfbe-a7b7e3629b0a'	System	24 Aug 2020 20:03:11
User entered 'None (1)'	System	24 Aug 2020 20:03:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:02:44', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0d730ab1-a81e-431f-bfbe-a7b7e3629b0a'	System	24 Aug 2020 20:03:11
User entered 'No (N)'	System	24 Aug 2020 20:03:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:02:51', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0d730ab1-a81e-431f-bfbe-a7b7e3629b0a'	System	24 Aug 2020 20:03:11
User entered 'No (N)'	System	24 Aug 2020 20:03:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:05', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0d730ab1-a81e-431f-bfbe-a7b7e3629b0a'	System	24 Aug 2020 20:03:11
User entered 'None (1)'	System	24 Aug 2020 20:03:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:08', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '0d730ab1-a81e-431f-bfbc-a7b7e3629b0a'	System	24 Aug 2020 20:03:11
User entered '24 Aug 2020 16:03'	System	24 Aug 2020 20:03:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 15:39'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:09'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:05:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '78fc2b0d-a242-45ec-97f8-d716513bca81'	System	25 Aug 2020 00:06:13
User entered 'None (1)'	System	25 Aug 2020 00:06:13

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:05:39', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '78fc2b0d-a242-45ec-97f8-d716513bca81'	System	25 Aug 2020 00:06:13
User entered 'No (N)'	System	25 Aug 2020 00:06:13

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:05:48', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '78fc2b0d-a242-45ec-97f8-d716513bca81'	System	25 Aug 2020 00:06:13
User entered 'No (N)'	System	25 Aug 2020 00:06:13

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:04', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '78fc2b0d-a242-45ec-97f8-d716513bca81'	System	25 Aug 2020 00:06:13
User entered 'None (1)'	System	25 Aug 2020 00:06:13

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:11', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '78fc2b0d-a242-45ec-97f8-d716513bca81'	System	25 Aug 2020 00:06:13
User entered '24 Aug 2020 20:06'	System	25 Aug 2020 00:06:13

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:04'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 2'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:23', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'd7b4250e-d331-4155-b2c2-14ab4da0a706'	System	26 Aug 2020 04:07:01
User entered 'None (1)'	System	26 Aug 2020 04:07:01

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:31', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'd7b4250e-d331-4155-b2c2-14ab4da0a706'	System	26 Aug 2020 04:07:01
User entered 'No (N)'	System	26 Aug 2020 04:07:01

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:39', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'd7b4250e-d331-4155-b2c2-14ab4da0a706'	System	26 Aug 2020 04:07:01
User entered 'No (N)'	System	26 Aug 2020 04:07:01

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:54', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'd7b4250e-d331-4155-b2c2-14ab4da0a706'	System	26 Aug 2020 04:07:01
User entered 'None (1)'	System	26 Aug 2020 04:07:01

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:57', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'd7b4250e-d331-4155-b2c2-14ab4da0a706'	System	26 Aug 2020 04:07:01
User entered '26 Aug 2020 00:06'	System	26 Aug 2020 04:07:01

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 3'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T13:32:31', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '357c613d-cb09-44ee-9f2b-3baf5fb0768d'	System	26 Aug 2020 17:33:04
User entered 'None (1)'	System	26 Aug 2020 17:33:04

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T13:32:36', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '357c613d-cb09-44ee-9f2b-3baf5fb0768d'	System	26 Aug 2020 17:33:04
User entered 'No (N)'	System	26 Aug 2020 17:33:04

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T13:32:38', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '357c613d-cb09-44ee-9f2b-3baf5fb0768d'	System	26 Aug 2020 17:33:04
User entered 'No (N)'	System	26 Aug 2020 17:33:04

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T13:32:57', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '357c613d-cb09-44ee-9f2b-3baf5fb0768d'	System	26 Aug 2020 17:33:04
User entered 'None (1)'	System	26 Aug 2020 17:33:04

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T13:33:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '357c613d-cb09-44ee-9f2b-3baf5fb0768d'	System	26 Aug 2020 17:33:04
User entered '26 Aug 2020 13:33'	System	26 Aug 2020 17:33:04

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 4'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:44', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f48a1f82-0068-4149-b97f-f78a9e412936'	System	27 Aug 2020 22:50:11
User entered 'None (1)'	System	27 Aug 2020 22:50:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:47', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f48a1f82-0068-4149-b97f-f78a9e412936'	System	27 Aug 2020 22:50:11
User entered 'No (N)'	System	27 Aug 2020 22:50:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:49:50', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f48a1f82-0068-4149-b97f-f78a9e412936'	System	27 Aug 2020 22:50:11
User entered 'No (N)'	System	27 Aug 2020 22:50:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:02', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f48a1f82-0068-4149-b97f-f78a9e412936'	System	27 Aug 2020 22:50:11
User entered 'None (1)'	System	27 Aug 2020 22:50:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:08', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'f48a1f82-0068-4149-b97f-f78a9e412936'	System	27 Aug 2020 22:50:11
User entered '27 Aug 2020 18:50'	System	27 Aug 2020 22:50:11

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 5'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a228f6cb-deb1-4a8c-ba3d-6e941ea826c7'	System	29 Aug 2020 01:25:21
User entered 'None (1)'	System	29 Aug 2020 01:25:21

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:03', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a228f6cb-deb1-4a8c-ba3d-6e941ea826c7'	System	29 Aug 2020 01:25:21
User entered 'No (N)'	System	29 Aug 2020 01:25:21

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:08', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a228f6cb-deb1-4a8c-ba3d-6e941ea826c7'	System	29 Aug 2020 01:25:21
User entered 'No (N)'	System	29 Aug 2020 01:25:21

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:17', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a228f6cb-deb1-4a8c-ba3d-6e941ea826c7'	System	29 Aug 2020 01:25:21
User entered 'None (1)'	System	29 Aug 2020 01:25:21

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:19', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a228f6cb-deb1-4a8c-ba3d-6e941ea826c7'	System	29 Aug 2020 01:25:21
User entered '28 Aug 2020 21:25'	System	29 Aug 2020 01:25:21

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 6'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:36', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'c43a8628-ee3d-417b-9f78-66909f4a10c3'	System	30 Aug 2020 00:45:47
User entered 'None (1)'	System	30 Aug 2020 00:45:47

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:38', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'c43a8628-ee3d-417b-9f78-66909f4a10c3'	System	30 Aug 2020 00:45:47
User entered 'No (N)'	System	30 Aug 2020 00:45:47

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'c43a8628-ee3d-417b-9f78-66909f4a10c3'	System	30 Aug 2020 00:45:47
User entered 'No (N)'	System	30 Aug 2020 00:45:47

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:42', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'c43a8628-ee3d-417b-9f78-66909f4a10c3'	System	30 Aug 2020 00:45:47
User entered 'None (1)'	System	30 Aug 2020 00:45:47

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:44', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'c43a8628-ee3d-417b-9f78-66909f4a10c3'	System	30 Aug 2020 00:45:47
User entered '29 Aug 2020 20:45'	System	30 Aug 2020 00:45:47

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 7'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'ad34e224-3c55-4e17-a1f4-cf51d3b3049b'	System	31 Aug 2020 00:19:52
User entered 'None (1)'	System	31 Aug 2020 00:19:52

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:42', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'ad34e224-3c55-4e17-a1f4-cf51d3b3049b'	System	31 Aug 2020 00:19:52
User entered 'No (N)'	System	31 Aug 2020 00:19:52

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:45', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'ad34e224-3c55-4e17-a1f4-cf51d3b3049b'	System	31 Aug 2020 00:19:52
User entered 'No (N)'	System	31 Aug 2020 00:19:52

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:47', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'ad34e224-3c55-4e17-a1f4-cf51d3b3049b'	System	31 Aug 2020 00:19:52
User entered 'None (1)'	System	31 Aug 2020 00:19:52

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:49', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'ad34e224-3c55-4e17-a1f4-cf51d3b3049b'	System	31 Aug 2020 00:19:52
User entered '30 Aug 2020 20:19'	System	31 Aug 2020 00:19:52

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:22', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:26', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:43', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:47', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:50', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:52', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'None (0)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:03:58', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered 'No (N)'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T16:04:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '8e7c7f2d-450a-4a0d-8b8a-9cd685d94b65'	System	24 Aug 2020 20:04:02
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 20:04:02

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 15:39'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 18:09'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:21', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:33', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:38', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:43', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:45', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'None (0)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:53', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered 'No (N)'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-24T20:06:59', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '9ddd02c9-46fb-4fab-af53-d01a8fa7a24f'	System	25 Aug 2020 00:07:07
User entered '24 Aug 2020 20:06'	System	25 Aug 2020 00:07:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '24 Aug 2020 19:04'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 2'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:05:50', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:05:52', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:05:56', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:05:58', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:01', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:03', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'None (0)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:08', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered 'No (N)'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-26T00:06:12', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '159f6873-f582-4bf0-9444-9965f67c197a'	System	26 Aug 2020 04:06:14
User entered '26 Aug 2020 00:06'	System	26 Aug 2020 04:06:14

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 3'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:09', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:11', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:12', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:14', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:16', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:18', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'None (0)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:22', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered 'No (N)'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T07:39:24', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '3cdb2722-4d53-4a25-9d8e-616dcb761fcf'	System	27 Aug 2020 11:39:26
User entered '27 Aug 2020 07:39'	System	27 Aug 2020 11:39:26

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 4'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:12', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:18', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:20', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:22', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:24', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:25', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'None (0)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:30', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered 'No (N)'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-27T18:50:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '36fb1369-2432-4cab-9a70-14b43978cff4'	System	27 Aug 2020 22:50:36
User entered '27 Aug 2020 18:50'	System	27 Aug 2020 22:50:36

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 5'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:25', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:27', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:28', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:30', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:34', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'None (0)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:38', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered 'No (N)'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-28T21:25:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '47694e8c-633c-4771-b7a4-244c6a586997'	System	29 Aug 2020 01:25:42
User entered '28 Aug 2020 21:25'	System	29 Aug 2020 01:25:42

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 6'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:48', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered 'None (0)'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:49', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered 'None (0)'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:51', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered 'None (0)'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:53', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa' User entered 'None (0)'	System	30 Aug 2020 00:46:07
	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:54', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa' User entered 'None (0)'	System	30 Aug 2020 00:46:07
	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:56', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered 'None (0)'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:45:59', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afec-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered 'No (N)'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-29T20:46:02', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'a0a4bd49-0b05-422e-afee-9258abdbf5fa'	System	30 Aug 2020 00:46:07
User entered '29 Aug 2020 20:46'	System	30 Aug 2020 00:46:07

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 7'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:53', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:55', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:57', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:19:58', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:20:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:20:02', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'None (0)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:20:06', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered 'No (N)'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-08-30T20:20:08', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4fe0f8a5-d076-43c6-af92-54961e0ebf13'	System	31 Aug 2020 00:20:11
User entered '30 Aug 2020 20:20'	System	31 Aug 2020 00:20:11

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:52:18

US3372229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:06
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:54:54

US3372229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:06
User entered '31 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:54:54

US3372229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:06
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:54:54

US3372229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:06
User entered empty.	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:54:54

US3372229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:23
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:02

US3372229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'I'	System	07 Sep 2020 15:55:02

US3372229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:32
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:15

US3372229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:32
User entered '7 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:15

US3372229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:32
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:15

US3372229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:32
User entered empty.	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:15

US3372229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 17:44:44
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Sep 2020 15:55:19

US3372229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'I'	System	07 Sep 2020 15:55:19

US3372229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:19:03
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:52:50

US3372229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:19:03
User entered '15 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:52:50

US3372229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:19:03
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:52:50

US3372229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:19:03
User entered empty.	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:52:50

US3372229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:19:16
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	28 Sep 2020 17:29:37

US3372229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:31
User entered 'I'	System	28 Sep 2020 17:29:37

US3372229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:36:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:19:39

US3372229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:36:27
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:19:39

US3372229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[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 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:36:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Sep 2020 19:19:39

US3372229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'VISIT2'	System	28 Sep 2020 19:19:39

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '28 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '13:05'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '28 Sep 2020 13:05'	System	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '36.8' C	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '62'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'bpm'	System	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '14'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'breaths/min'	System	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '100'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'mmHg'	System	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered '74'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'mmHg'	System	09 Oct 2020 20:42:13

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:09

US3372229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:36:38
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:15

US3372229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:36:38
User entered '28 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:15

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered '28 Sep 2020'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered 'Urine (URINE)'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 06:58:19
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:18
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy test is positive and Pregnancy forms have been submitted to IQVIA' (Site from System).	Mary Sergalis (b) (4)	28 Sep 2020 21:06:56
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	28 Sep 2020 21:06:11
User entered 'Positive (POSITIVE)'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
User closed query 'Per CDM: Please be aware that "Collection date" and "Collection time" are for FSH not pregnancy test. Please consider removing date and time if FSH was not taken. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:59:13
Query 'Per CDM: Please be aware that "Collection date" and "Collection time" are for FSH not pregnancy test. Please consider removing date and time if FSH was not taken. Thank you!' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:27:40
User opened query 'Per CDM: Please be aware that "Collection date" and "Collection time" are for FSH not pregnancy test. Please consider removing date and time if FSH was not taken. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:12:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:27:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Un-verified.	Peter Jacob (b) (4)	09 Oct 2020 20:27:35
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	09 Oct 2020 20:27:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered '28 Sep 2020'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:27:40
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Un-verified.	Peter Jacob (b) (4)	09 Oct 2020 20:27:35
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	09 Oct 2020 20:27:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:18
User entered '13:15'	Mary Sergalis (b) (4)	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:27:35
User entered '28 Sep 2020 13:15'	System	28 Sep 2020 21:06:11

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		11 Oct 2020 23:41:30
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	11 Oct 2020 23:41:30
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	09 Oct 2020 20:43:23
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

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)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 19:37:04
User entered empty.	System	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:23

US3372229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:13
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:37

US3372229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:13
User entered '28 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:37

US3372229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:21:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:13
User entered '13:32'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:37

US3372229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '28 Sep 2020 13:32'	System	09 Oct 2020 20:43:37

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:52
User entered '28 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:52
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:52
User entered '13:31'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '28 Sep 2020 13:31'	System	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:52
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:19:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:38:52
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	09 Oct 2020 20:43:45

US3372229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:00
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:43:49

US3372229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '1'	System	09 Oct 2020 20:43:49

US3372229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:08
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered 'No (N)'	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:29

US3372229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:08
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:29

US3372229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:08
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:29

US3372229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:08
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:29

US3372229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:08:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:38:58

US3372229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'I'	System	19 Oct 2020 15:38:58

US3372229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered 'No (N)'	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:36

US3372229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:36

US3372229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:36

US3372229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:30:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:36

US3372229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:08:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:39:28

US3372229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'I'	System	19 Oct 2020 15:39:28

US3372229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:31:19
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered 'No (N)'	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:41

US3372229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:31:19
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:41

US3372229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:31:19
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:41

US3372229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:31:19
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	19 Oct 2020 15:52:41

US3372229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:08:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:39:38

US3372229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'I'	System	19 Oct 2020 15:39:38

US3372229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:57
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 12:36:38
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 20:56:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 08:46:05
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 19:40:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:35:20

US3372229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:11
User closed query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 19Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:21:27
Query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 19Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:47
User opened query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 19Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:32:28
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:35:20

US3372229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[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 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Oct 2020 16:35:20

US3372229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'VISIT3'	System	19 Oct 2020 16:35:20

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:20
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered empty.	System	03 Nov 2020 22:42:59

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43

US3372229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43

US3372229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:40
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:05

US3372229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:40
User entered empty.	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:05

US3372229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:49
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:19

US3372229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:49
User entered '19 Oct 2020'	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:19

US3372229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:02:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:49
User entered '13:01'	Peter Jacob (b) (4) (b) (4)	03 Nov 2020 22:43:19

US3372229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '19 Oct 2020 13:01'	System	03 Nov 2020 22:43:19

US3372229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:40:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:35:28

US3372229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered '1'	System	19 Oct 2020 16:35:28

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 64'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-24T00:49:17', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'da3f1543-e679-4881-be23-83cec9cd6235'	System	24 Oct 2020 04:49:41
User entered 'No (N)'	System	24 Oct 2020 04:49:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-24T00:49:31', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'da3f1543-e679-4881-be23-83cec9cd6235'	System	24 Oct 2020 04:49:41
User entered 'No (N)'	System	24 Oct 2020 04:49:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-24T00:49:40', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'da3f1543-e679-4881-be23-83cec9cd6235' User entered '24 Oct 2020 00:49:40'	System	24 Oct 2020 04:49:41
	System	24 Oct 2020 04:49:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 71'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:22', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered 'Yes (Y)'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:29', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered 'No (N)'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:35', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered 'No (N)'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:42', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered 'Yes (Y)'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:49', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-10-31T09:37:52', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '4169b88a-7b1d-42f2-9bf6-c2515f237104'	System	31 Oct 2020 13:38:02
User entered '31 Oct 2020 09:37:52'	System	31 Oct 2020 13:38:02

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:00:51
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41
Data entry locked.	System	24 Aug 2020 19:52:18
User entered 'Day 78'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 19:52:18

US3372229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	14 Apr 2021 18:05:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:41
Data entry locked.	System	24 Aug 2020 19:52:18
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 19:52:18

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-02T07:10:27', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'dddfde44-4ead-49c3-aead-e04ee5e1b239'	System	02 Dec 2020 12:10:39
User entered 'No (N)'	System	02 Dec 2020 12:10:39

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-02T07:10:32', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'dddfde44-4ead-49c3-aead-e04ee5e1b239'	System	02 Dec 2020 12:10:39
User entered 'No (N)'	System	02 Dec 2020 12:10:39

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-02T07:10:36', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'dddfe44-4ead-49c3-aead-e04ee5e1b239'	System	02 Dec 2020 12:10:39
User entered '02 Dec 2020 07:10:36'	System	02 Dec 2020 12:10:39

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-23T17:04:52', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e6c2cc18-13c5-45ec-8b6c-a4d8f3a35300'	System	23 Dec 2020 22:05:02
User entered 'No (N)'	System	23 Dec 2020 22:05:02

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-23T17:04:55', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e6c2cc18-13c5-45ec-8b6c-a4d8f3a35300'	System	23 Dec 2020 22:05:02
User entered 'No (N)'	System	23 Dec 2020 22:05:02

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2020-12-23T17:04:59', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e6c2cc18-13c5-45ec-8b6c-a4d8f3a35300'	System	23 Dec 2020 22:05:02
User entered '23 Dec 2020 17:04:59'	System	23 Dec 2020 22:05:02

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-01-27T08:23:47', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '884ea7ac-8fc9-4d63-bafb-b6c5ff646e9f'	System	27 Jan 2021 13:23:56
User entered 'No (N)'	System	27 Jan 2021 13:23:56

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-01-27T08:23:50', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '884ea7ac-8fc9-4d63-bafb-b6c5ff646e9f'	System	27 Jan 2021 13:23:56
User entered 'No (N)'	System	27 Jan 2021 13:23:56

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-01-27T08:23:53', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '884ea7ac-8fc9-4d63-bafb-b6c5ff646e9f' User entered '27 Jan 2021 08:23:53'	System	27 Jan 2021 13:23:56
	System	27 Jan 2021 13:23:56

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-03T06:55:16', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e4daec92-d8b1-43db-b53e-58b6c2cd774c'	System	03 Feb 2021 13:55:26
User entered 'No (N)'	System	03 Feb 2021 13:55:26

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-03T06:55:20', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e4daec92-d8b1-43db-b53e-58b6c2cd774c'	System	03 Feb 2021 13:55:26
User entered 'No (N)'	System	03 Feb 2021 13:55:26

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-03T06:55:23', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: 'e4daec92-d8b1-43db-b53e-58b6c2cd774c'	System	03 Feb 2021 13:55:26
User entered '03 Feb 2021 06:55:23'	System	03 Feb 2021 13:55:26

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-24T06:29:07-05:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '40ceae6e-c0a4-4f15-b94b-6d8e5b4495db' User entered 'No (N)'	System	24 Feb 2021 11:29:19
	System	24 Feb 2021 11:29:19

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

Have you been exposed to someone with 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)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-24T06:29:04-05:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '40ceae6e-c0a4-4f15-b94b-6d8e5b4495db'	System	24 Feb 2021 11:29:19
User entered 'No (N)'	System	24 Feb 2021 11:29:19

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1fc4b44551999846)', Time: '2021-02-24T06:29:14-05:00', User OID: 'PatientReportedOutcome (US3372229)', ODM File OID: '40ceae6e-c0a4-4f15-b94b-6d8e5b4495db' User entered '24 Feb 2021 06:29:14'	System	24 Feb 2021 11:29:19
	System	24 Feb 2021 11:29:19

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:50:41

US3372229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:41
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:50:41

US3372229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:41:26
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4)	23 Nov 2020 21:21:45

US3372229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:41:26
User entered '23 Nov 2020'	Danielle Theodore (b) (4) (b) (4)	23 Nov 2020 21:21:45

US3372229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:41:26
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4) (b) (4)	23 Nov 2020 21:21:45

US3372229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:41:26
User entered empty.	Danielle Theodore (b) (4) (b) (4)	23 Nov 2020 21:21:45

US3372229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:41:35
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4)	23 Nov 2020 21:21:52

US3372229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:39:43
User entered 'I'	System	23 Nov 2020 21:21:52

US3372229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 15:08:37

US3372229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered '27 Dec 2020'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 15:08:37

US3372229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 15:08:37

US3372229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:36:01
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 15:08:37

US3372229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Dec 2020 15:08:47

US3372229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User entered 'I'	System	27 Dec 2020 15:08:47

US3372229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:17:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:00:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 15:38:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:36:11
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 14:01:27

US3372229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, updating data in Covid -19 Assessment eCRF for swab sample if collected on 14-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:18:06
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, updating data in Covid -19 Assessment eCRF for swab sample if collected on 14-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, else clarify. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:00:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 15:38:48
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, updating data in Covid -19 Assessment eCRF for swab sample if collected on 14-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:27:09
User entered '27 Jan 2021'	Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 14:01:27

US3372229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:17:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:00:47
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 15:38:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:36:24
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 14:01:27

US3372229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:38:48
User entered empty.	Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 14:01:27

US3372229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:38:56
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 14:01:33

US3372229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User entered 'I'	System	27 Jan 2021 14:01:33

US3372229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:25
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 14:24:32
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Feb 2021 20:06:34

US3372229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:25
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 14:24:32
User entered '18 Feb 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Feb 2021 20:06:34

US3372229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:25
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 14:24:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Feb 2021 20:06:34

US3372229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:25
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 14:24:32
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Feb 2021 20:06:34

US3372229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:40:49
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 14:24:32
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Feb 2021 20:07:16

US3372229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:30
User entered 'I'	System	18 Feb 2021 20:07:16

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:17:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:50:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	19 Apr 2021 19:07:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:38:53
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:42:08
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 14:42:08
User entered '10:17' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 14:42:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:17:29
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '11:20'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:50:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '14 Jan 2021 10:17'	System	19 Apr 2021 14:42:08
User entered '14 Jan 2021 11:20'	System	22 Feb 2021 21:50:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	19 Apr 2021 19:07:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:38:58
User closed query 'According to eMR type of contact was a call and the time is not clear. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:38:55
Query 'According to eMR type of contact was a call and the time is not clear. Please review and update accordingly. ' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 14:42:28
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:42:08
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 14:42:08
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 14:42:08
User opened query 'According to eMR type of contact was a call and the time is not clear. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:17:31
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:50:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:17:33
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:50:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User closed query 'According to eMR 1st day of symptom was 12DEc2020, please add the missing days (12&13Dec2020). Thanks!' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:56:29
Query 'According to eMR 1st day of symptom was 12DEc2020, please add the missing days (12&13Dec2020). Thanks!' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:27:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User opened query 'According to eMR 1st day of symptom was 12DEc2020, please add the missing days (12&13Dec2020). Thanks!' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:19:41
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '98'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '98.0' F	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User closed query 'Please update sore throat, nasal congestion and rhinorrhea as well. Thans!' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 18:27:14
Query 'Please update sore throat, nasal congestion and rhinorrhea as well. Thans!' answered with 'data updated' (Site from CRA).	Peter Jacob (b) (4) (b) (4)	28 Apr 2021 23:01:00
User opened query 'Please update sore throat, nasal congestion and rhinorrhea as well. Thans!' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:05:13
User closed query 'According to the AE log on medical records: Sore throat, cough, nasal congestion and rhinorrhea were 'mild', please update the symptom log accordingly. Thanks!' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:05:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Apr 2021 19:19:34
Query 'According to the AE log on medical records: Sore throat, cough, nasal congestion and rhinorrhea were 'mild', please update the symptom log accordingly. Thanks!' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:28:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:07
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 19:28:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 19:28:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User opened query 'According to the AE log on medical records: Sore throat, cough, nasal congestion and rhinorrhea were 'mild', please update the symptom log accordingly. Thanks!' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:27:38
User signature succeeded.	Mira Baron (b) (4) (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:27:03
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:27:05
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:27:11
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:20:59
DataPoint Un-verified.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	28 Apr 2021 23:00:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:04

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '15 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '99'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '98.0' F	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 21:52:22
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 21:52:22
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 21:52:22
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:51:56

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	22 Mar 2021 13:21:39
User closed query 'per CDM: please confirm date for day 5, as day 4 noted as 15 Jan 2021' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:25:49
Query 'per CDM: please confirm date for day 5, as day 4 noted as 15 Jan 2021' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 15:43:40
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 15:43:25
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:43:25
User opened query 'per CDM: please confirm date for day 5, as day 4 noted as 15 Jan 2021' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:10:36
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '97'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '97.1' F	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:53:20

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '100'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '97.1' F	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:54:18

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '99'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '97.2' F	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:01

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '99'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '97.6' F	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:27:44
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'None (None)'	(b) (4), (b) (6)	22 Feb 2021 21:55:47

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered '12 Jan 2021'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:24:29

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered '13 Jan 2021'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '%'	System	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'None (None)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:49
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:19:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Apr 2021 19:26:12

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '0'	System	22 Feb 2021 21:57:09

US3372229

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:39:46

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:18:42
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 21:57:23

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	22 Feb 2021 21:59:48

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:13
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:59:48

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:13
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:59:48

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	22 Feb 2021 22:00:16

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:13
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 22:00:16

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:13
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '18 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 22:00:16

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: User entered 'Day 7 (Day 7)'	System	27 Mar 2021 11:30:15
Amendment Manager: User entered 'Day 7 (Day 7)'	System	06 Mar 2021 13:49:06
Amendment Manager: User entered 'Day 7 (Day 7)'	System	27 Feb 2021 17:40:09

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: User entered 'Day 9 (Day 9)'	System	27 Mar 2021 11:30:15
Amendment Manager: User entered 'Day 9 (Day 9)'	System	06 Mar 2021 13:49:06
Amendment Manager: User entered 'Day 9 (Day 9)'	System	27 Feb 2021 17:40:09

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: User entered 'Day 14 (Day 14)'	System	27 Mar 2021 11:30:15
Amendment Manager: User entered 'Day 14 (Day 14)'	System	06 Mar 2021 13:49:06
Amendment Manager: User entered 'Day 14 (Day 14)'	System	27 Feb 2021 17:40:09

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: User entered 'Day 21 (Day 21)'	System	27 Mar 2021 11:30:15
Amendment Manager: User entered 'Day 21 (Day 21)'	System	06 Mar 2021 13:49:06
Amendment Manager: User entered 'Day 21 (Day 21)'	System	27 Feb 2021 17:40:09

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
Amendment Manager: User entered 'Day 28 (Day 28)'	System	27 Mar 2021 11:30:15
Amendment Manager: User entered 'Day 28 (Day 28)'	System	06 Mar 2021 13:49:06
Amendment Manager: User entered 'Day 28 (Day 28)'	System	27 Feb 2021 17:40:09

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:08:47
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:08:47
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:08:47
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered 'SICKD1'	System	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '11:20'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '14 Jan 2021 11:20'	System	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '167.6' cm	(b) (4), (b) (6)	22 Feb 2021 21:58:46
DataPoint set to visible.	System	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '87.5' kg	(b) (4), (b) (6)	22 Feb 2021 21:58:46
DataPoint set to visible.	System	22 Feb 2021 21:57:44

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '36.7' C	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'infrared forehead'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '73'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered 'bpm'	System	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '18'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered 'breaths/min'	System	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '100'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered 'mmHg'	System	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:10:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '70'	(b) (4), (b) (6)	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered 'mmHg'	System	22 Feb 2021 21:58:46

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:12:35
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:59:15

US3372229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:12:35
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Feb 2021 21:59:15

US3372229

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:39:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:04
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 21:59:26

US3372229

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:39:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:14:04
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:59:26

US3372229

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User closed query 'Please complete module Safety Call OL-D8. Thanks. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 12:21:34
Query 'Please complete module Safety Call OL-D8. Thanks. ' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:24:33
User opened query 'Please complete module Safety Call OL-D8. Thanks. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:51:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:39:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:35:07

US3372229

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:39:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:35:07

US3372229

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[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 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:39:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:14:18
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Jan 2021 19:35:07

US3372229

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 19:35:07

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
	(b) (4)	
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[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 16:06:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:57
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:49:07

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:23:57
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:49:07

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User signature succeeded.	Mira Baron (b) (4)	19 Apr 2021 19:07:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:44
User closed query 'According to eMR subject did not received the second dose. Please update. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:07:21
Query 'According to eMR subject did not received the second dose. Please update. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:37:42
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:37:20
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 17:37:20
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 17:37:20
User opened query 'According to eMR subject did not received the second dose. Please update. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:40:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:15
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:11:45
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:11:45
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:58:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered 'I'	System	27 Jan 2021 19:35:29

US3372229

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:11:45
User entered 'I'	System	27 Jan 2021 19:35:29

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:00
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:00
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '27 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '10:30'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:34
User entered '27 Jan 2021 10:30'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '37' C	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered 'Other (Other)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered 'forehead'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered '71'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:34
User entered 'bpm'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered '17'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:34
User entered 'breaths/min'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '133'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:34
User entered 'mmHg'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:34
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '83'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:34
User entered 'mmHg'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:40:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:00
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '27 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '12:08'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:57
User entered '27 Jan 2021 12:08'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '36.9' C	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered 'Other (Other)'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
	(b) (4)	
User entered 'forehead'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '61'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:57
User entered 'bpm'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '17'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:57
User entered 'breaths/min'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '125'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:57
User entered 'mmHg'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:41:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:10:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:47:03
User entered '88'	(b) (4), (b) (6)	29 Jan 2021 20:24:08

US3372229

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:10:57
User entered 'mmHg'	System	29 Jan 2021 20:24:08

US3372229

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:20
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:24:16

US3372229

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:20
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:08:24
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:24:16

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User closed query 'Please verify, noted in source as not receiving treatment.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 19:11:54
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Comment added 'data updated, did not mean to send that'.	Peter Jacob (b) (4)	20 Feb 2021 23:12:21
	(b) (4)	
Query 'Please verify, noted in source as not receiving treatment.' answered with 'he lived far from the office and did not want to drive for more than one hour to complete the visits' (Site from CRA).	Peter Jacob (b) (4)	20 Feb 2021 23:12:10
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:06
	(b) (4)	
User opened query 'Please verify, noted in source as not receiving treatment.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:24:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	20 Feb 2021 23:12:27
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:27
	(b) (4)	
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	20 Feb 2021 23:12:06
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:12:06
DataPoint set to visible.	System	20 Feb 2021 23:11:45
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jan 2021 20:25:41
DataPoint set to invisible.	System	27 Jan 2021 19:35:29

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:06
User entered '27 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:06
User entered '11:26'	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:12:06
User entered '27 Jan 2021 11:26'	System	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:06
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:27
User entered empty.	System	20 Feb 2021 23:12:06
User entered 'ONCE'	System	29 Jan 2021 20:25:41

US3372229

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered empty.	System	20 Feb 2021 23:12:06
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 20:25:41

US3372229

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:56
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is marked not done in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mira Baron (b) (4)	02 Mar 2021 12:51:01 24 Feb 2021 20:52:24
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is marked not done in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM). Signature has been broken.	(b) (4) Peter Jacob (b) (4)	24 Feb 2021 16:12:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:12:45
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is marked not done in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mira Baron (b) (4)	24 Feb 2021 14:36:02 23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:40
User entered 'No (N)' reason for change: Data Entry Error User signature succeeded.	(b) (4) Peter Jacob (b) (4)	20 Feb 2021 23:12:40
User entered 'Yes (Y)'	Mira Baron (b) (4) (b) (4), (b) (6)	17 Feb 2021 00:04:11 27 Jan 2021 19:35:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

1482 of 1890

US3372229

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:56
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:24
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	24 Feb 2021 16:12:45
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:12:45
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:40
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:11
	(b) (4)	
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:35:48

US3372229

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:42:56
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:24
Signature has been broken.	Peter Jacob (b) (4)	24 Feb 2021 16:12:45
User entered '08:39' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:12:45
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Feb 2021 23:12:42
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Feb 2021 23:12:40
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:40
User entered ':39' (non-conformant).	Peter Jacob (b) (4)	20 Feb 2021 23:12:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:04:11
User entered '08:39'	(b) (4), (b) (6)	27 Jan 2021 19:35:48

US3372229

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered '27 Jan 2021 08:39'	System	24 Feb 2021 16:12:45
User entered empty.	System	20 Feb 2021 23:12:40
User entered '27 Jan 2021 08:39'	System	27 Jan 2021 19:35:48

US3372229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:43:10
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:24
Signature has been broken.	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:39:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:36:08

US3372229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:43:10
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:24
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:39:59
	(b) (4)	
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:36:08

US3372229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:43:10
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:52:24
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
	(b) (4)	
User entered '08:37' reason for change: Data Entry Error	Peter Jacob (b) (4)	24 Feb 2021 16:13:09
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
Signature has been broken.	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	20 Feb 2021 23:12:51
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:39:59
	(b) (4)	
User entered '08:37'	(b) (4), (b) (6)	27 Jan 2021 19:36:08

US3372229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered '27 Jan 2021 08:37'	System	24 Feb 2021 16:13:09
User entered empty.	System	20 Feb 2021 23:12:51
User entered '27 Jan 2021 08:37'	System	27 Jan 2021 19:36:08

US3372229

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

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:43:53
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:42:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:36:14

US3372229

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

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:06:17
User entered 'I'	System	27 Jan 2021 19:36:14

US3372229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:22:15
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 17:24:16

US3372229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:22:15
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:24:16

US3372229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:22:15
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:24:16

US3372229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:22:15
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:16

US3372229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:22:18
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 17:24:21

US3372229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	13 Apr 2021 17:24:21

US3372229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	13 Apr 2021 17:24:21
DataPoint set to visible.	System	13 Apr 2021 17:24:21

US3372229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:39:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:02:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:46:41
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:31:52

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:03:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
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)	17 Dec 2020 13:21:40
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 'hyperemesis is due to pregnancy ' (Site from DM).	Peter Jacob (b) (4)	15 Dec 2020 15:29:28
	(b) (4)	
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)	14 Dec 2020 17:12:49
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Hyperemesis - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 04:00:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 04:00:18
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 14:34:00
User entered 'Hyperemesis'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:03:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:03:56
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:03:58
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '30 Oct 2020'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User entered empty.	System	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:37
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 17:55:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 17:55:25
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	21 Apr 2021 20:54:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Apr 2021 17:55:25
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:55:25
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 17:55:25
User entered 'un Feb 2021' (non-conformant).	(b) (4), (b) (6)	14 Apr 2021 17:55:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:46
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User entered empty.	System	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:52
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:04:57
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:34
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:33
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:32
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:28
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:25
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:23
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:21
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:42:53
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 18:50:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 18:50:09
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:17:45
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:14
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'I'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:47
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 17:55:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 17:55:25
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:09
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:05:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User entered '0'	System	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10
User entered '1'	System	02 Nov 2020 14:33:01

US3372229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:10

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
User closed query 'According to eMR subject had sore throat, cough, nasal congestions and rhinorrhea in January. Please review and update or clarify. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:23:14
Query 'According to eMR subject had sore throat, cough, nasal congestions and rhinorrhea in January. Please review and update or clarify. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:14:38
User opened query 'According to eMR subject had sore throat, cough, nasal congestions and rhinorrhea in January. Please review and update or clarify. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:10:26
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:12:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:12:04
Data point term sent to Coder	System	02 Nov 2020 14:35:01
User entered 'Dehydration'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '30 Oct 2020'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
User entered empty.	System	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '30 Oct 2020'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
User entered empty.	System	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:43:01
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 18:51:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 18:51:14
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:18:06
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'l'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:06:01
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:39:01
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
User entered '0'	System	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15
User entered '1'	System	02 Nov 2020 14:34:07

US3372229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:15

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:00:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:00:52
Data point term sent to Coder	System	14 Apr 2021 17:59:52
User entered 'Pregnancy'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 05:48:52
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Data updated.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 18:07:05
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Apr 2021 17:59:09
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'l'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '0'	System	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '1'	System	14 Apr 2021 17:59:09

US3372229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: 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)	14 Apr 2021 18:14:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:14:06
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 18:11:22
User entered 'Sore Throat'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '12 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User entered empty.	System	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '17 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User entered empty.	System	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'l'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User entered '0'	System	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47
User entered '0'	System	14 Apr 2021 18:10:07

US3372229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:47

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:14:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:14:31
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 18:12:37
User entered 'Cough'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '12 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User entered empty.	System	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '19 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User entered empty.	System	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User entered '0'	System	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35
User entered '0'	System	14 Apr 2021 18:11:48

US3372229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:35

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:30:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:30:38
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 18:13:40
User entered 'Nasal Congestions'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '12 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User entered empty.	System	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '18 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User entered empty.	System	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'l'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User entered '0'	System	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59
User entered '0'	System	14 Apr 2021 18:13:05

US3372229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:59

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:15:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:15:53
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 18:14:48
User entered 'Rhinorrhea'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '12 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User entered empty.	System	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '18 Jan 2021'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User entered empty.	System	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:36:47
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User entered '0'	System	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40
User entered '0'	System	14 Apr 2021 18:14:07

US3372229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:39:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:57:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:39:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:10:51
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:46:13
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:34:29

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 04:33:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 04:33:11
Data point term sent to Coder	System	02 Nov 2020 14:36:02
User entered 'Influenza Vaccine'	Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:45:23
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:32:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:32:31
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:56:30
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Influenza Prophylaxis/Prevention'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0.5'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un Sep 2018'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un Sep 2018'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:35:45

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE;PERTUSSIS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:50:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:50:35
Data point term sent to Coder	System	02 Nov 2020 14:39:03
User entered 'Diphtheria Pertussis Vaccine'	Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:45:34
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:33:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:32:56
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:56:17
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'diphtheria/Tetanus and Acellular Pertussis Prophylaxis/Prevention'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0.5'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2017'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2017'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:38:06

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: ENCEPHALITIS VACCINES, PRODUCT: JAPANESE ENCEPHALITIS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:22:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:22:18
Data point term sent to Coder	System	02 Nov 2020 14:42:08
User entered 'Japanese Encephalitis Vaccine'	Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:45:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:33:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:33:34
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:56:58
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Japanese Encephalitis Prophylaxis/Prevention'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0.5'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:41:19
	Mary Sergalis (b) (4)	

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:41:19
	Mary Sergalis (b) (4)	

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2013'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2013'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:41:19

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: RABIES VACCINES, PRODUCT: RABIES VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:01:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:01:58
Data point term sent to Coder	System	02 Nov 2020 14:43:09
User entered 'Rabies Vaccine'	Mary Sergalis (b) (4) (b) (4) (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:46:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:33:54
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:57:18
User entered 'No (N)'	Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Rabies Prophylactic'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0.5'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:42:24
	Mary Sergalis (b) (4)	

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2013'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un UNK 2013'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:42:24

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 05:50:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:50:19
Data point term sent to Coder	System	02 Nov 2020 14:44:09
User entered 'Prozac'	Mary Sergalis (b) (4) (b) (4) (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Depression'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '40'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'once daily (QD)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Oral (ORAL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'un Feb 2019'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Yes (Y)'	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '1'	System	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '1'	System	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered '804 (804)'	System	02 Nov 2020 14:43:40

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User closed query 'According to eMR patient received the mRNA 1273 vaccine on 14Feb2021. Please review and reconcile or clarify. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:51:24
Query 'According to eMR patient received the mRNA 1273 vaccine on 14Feb2021. Please review and reconcile or clarify. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:47:58
User opened query 'According to eMR patient received the mRNA 1273 vaccine on 14Feb2021. Please review and reconcile or clarify. Thanks, (b) (6) (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:14:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 21:11:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	04 Nov 2020 21:11:55
Data point term sent to Coder	System	02 Nov 2020 14:45:10
User entered 'Zofran'	Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Hyperemesis'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '8'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'as needed (PRN)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Oral (ORAL)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '30 Oct 2020'	(b) (4)	
	Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered '0'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'Yes (Y)'	(b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered empty.	(b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:11:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:30:23
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
User entered empty.	System	02 Nov 2020 14:44:25

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 16:05:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 16:05:58
User signature succeeded.	Mira Baron (b) (4) (b) (4)	14 Apr 2021 15:54:13
Data point term sent to Coder	System	13 Apr 2021 17:47:24
User entered 'mRNA 1237 Vaccine'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'COVID-19 Prevention / Prophylaxis'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered '0.5'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:44
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
User entered empty.	System	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
User entered empty.	System	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:39:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:29
User entered empty.	System	13 Apr 2021 17:46:42

US3372229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:39:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:14:19
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:11:36
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Jan 2021 21:19:47

US3372229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:46

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:41
User closed query 'According to eMR subject withdrew consent on 01Mar2021. Please review and update accordingly. Thanks, (b) (6) (Site from CRA). Query 'According to eMR subject withdrew consent on 01Mar2021. Please review and update accordingly. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:06:54
User opened query 'According to eMR subject withdrew consent on 01Mar2021. Please review and update accordingly. Thanks, (b) (6) (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:06:06
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 12:47:52
User entered '28 Sep 2020'	(b) (4), (b) (6)	09 Apr 2021 12:44:58
	Mira Baron (b) (4)	23 Feb 2021 21:54:02
	(b) (4)	
	Mary Sergalis (b) (4)	10 Dec 2020 16:14:43

US3372229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:44:58
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User closed query 'Per CDM: Please confirm if subject is still participating in the study. According to protocol, subjects that requested unblinding (enter Part B: Open Label) are encouraged to remain in the ongoing study and continue with the original schedule of events (Part A: Blinded phase of study). Please review and update as needed, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:17:35
Query 'Per CDM: Please confirm if subject is still participating in the study. According to protocol, subjects that requested unblinding (enter Part B: Open Label) are encouraged to remain in the ongoing study and continue with the original schedule of events (Part A: Blinded phase of study). Please review and update as needed, else provide clarification. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Feb 2021 23:09:48
User opened query 'Per CDM: Please confirm if subject is still participating in the study. According to protocol, subjects that requested unblinding (enter Part B: Open Label) are encouraged to remain in the ongoing study and continue with the original schedule of events (Part A: Blinded phase of study). Please review and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 19:42:12
User closed query 'Per CDM: Please confirm reason for Dosing Discontinuation, as "Pregnancy" is recorded as reason second dose was not administered on Exposure CRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:56:11
User closed query 'Per CDM: Reason for discontinuation = SARS-COV-2, however corresponding AE is not recorded. Kindly verify and consider updating all the necessary eCRFs required else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:56:10

US3372229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Per CDM: Reason for discontinuation = SARS-COV-2, however corresponding AE is not recorded. Kindly verify and consider updating all the necessary eCRFs required else clarify. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Jan 2021 21:19:10
Query 'Per CDM: Please confirm reason for Dosing Discontinuation, as "Pregnancy" is recorded as reason second dose was not administered on Exposure CRF. Thank you.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Jan 2021 21:19:08
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Jan 2021 21:19:02
User opened query 'Per CDM: Please confirm reason for Dosing Discontinuation, as "Pregnancy" is recorded as reason second dose was not administered on Exposure CRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:58:58
User opened query 'Per CDM: Reason for discontinuation = SARS-COV-2, however corresponding AE is not recorded. Kindly verify and consider updating all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:44:32
User entered 'Due to SARS-COV-2 (COVID)'	Mary Sergalis (b) (4) (b) (4) (b) (4)	10 Dec 2020 16:14:43

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:44:58
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:54:02
User entered empty.	(b) (4) Mary Sergalis (b) (4)	10 Dec 2020 16:14:43

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 18:05:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:05:47
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:05:47
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:05:27
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
User signature succeeded.	Mira Baron (b) (4)	30 Apr 2021 13:45:39
User closed query 'Per CDM, per sponsor review: Per ConMed log, subject received a non-study EUA COVID vaccine on 14FEB2021, prior to the study discontinuation date. Please consider updating the reason for study discontinuation to "protocol deviation" else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 03:26:30
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:48:30
Query 'Per CDM, per sponsor review: Per ConMed log, subject received a non-study EUA COVID vaccine on 14FEB2021, prior to the study discontinuation date. Please consider updating the reason for study discontinuation to "protocol deviation" else clarify.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	29 Apr 2021 17:06:07
DataPoint Un-verified.	Peter Jacob (b) (4)	29 Apr 2021 16:34:14
Signature has been broken.	Peter Jacob (b) (4)	29 Apr 2021 16:34:14
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Peter Jacob (b) (4)	29 Apr 2021 16:34:14
User opened query 'Per CDM, per sponsor review: Per ConMed log, subject received a non-study EUA COVID vaccine on 14FEB2021, prior to the study discontinuation date. Please consider updating the reason for study discontinuation to "protocol deviation" else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:53:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
User entered 'Subject is pregnant and did not want to continue with the study. Consent was withdrawn.'	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:05:27

US3372229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:46

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:06:50
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:17:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:05:27