

US3372394 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:18:43

All time stamps listed in this document are displayed in GMT

US3372394

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:53:08

Generated On: 09 Jun 2021 17:18:43

[Participant ID](#)

US3372394

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

US3372394

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:23:14

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3372394

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:19:07

Generated On: 09 Jun 2021 17:18:43

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
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

US3372394

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:36:24

Generated On: 09 Jun 2021 17:18:43

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3372394

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:29:10

Generated On: 09 Jun 2021 17:18:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3372394

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 01:01:05

Generated On: 09 Jun 2021 17:18:43

Were any significant conditions reported?

Yes ☒
No ☐

US3372394

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372394

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3372394

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1976
Stop Year (derived)	1976

US3372394

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1976
Stop Year (derived)	1976

US3372394

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	FALLOPIAN TUBE FIMBRIAE FUSION
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

US3372394

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	BILATERAL CUFF TUBOPLASTY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

US3372394

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	FRACTURED RIGHT WRIST
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3372394

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	SURGICAL REDUCTION OF WRIST FRACTURE WITH EXTERNAL FIXATOR
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3372394

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	TOTAL HIP REPLACEMENT LEFT
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

US3372394

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	OSTEOARTHRITIS OF LEFT HIP
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

US3372394

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	TOTAL HIP REPLACEMENT RIGHT
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3372394

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	OSTEOARTHRITIS RIGHT HIP
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3372394

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	PELVIC INFLAMMATORY DISEASE
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3372394

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 00:45:28

Generated On: 09 Jun 2021 17:18:43

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

US3372394

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:39:25

Generated On: 09 Jun 2021 17:18:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:21 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:21
Height (<i>xxx.x</i>)	161.3 cm
Weight (<i>xxx.x</i>)	85.6 kg
BMI (<i>xxx.x</i>)	32.90069 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372394

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:16:56

Generated On: 09 Jun 2021 17:18:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3372394

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 18:05:35

Generated On: 09 Jun 2021 17:18:43

Date of assessment (dd MMM yyyy) 11 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1998

Date of last menstruation unknown False

US3372394

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:27:13

Generated On: 09 Jun 2021 17:18:43

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3372394

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:27:13

Generated On: 09 Jun 2021 17:18:43

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	

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:23:14

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 02:11:28

Generated On: 09 Jun 2021 17:18:43

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 190576

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 ☒

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:55:34

Generated On: 09 Jun 2021 17:18:43

Height	ND - Not Done
Weight	ND - Not Done

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:55:34

Generated On: 09 Jun 2021 17:18:43

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)	11 SEP 2020
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:21
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:55:34

Generated On: 09 Jun 2021 17:18:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:55
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3372394

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:16:56

Generated On: 09 Jun 2021 17:18:43

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.

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:54:05

Generated On: 09 Jun 2021 17:18:43

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 11:20

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

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:12:58

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	11 SEP 2020 10:50

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:30:23

Generated On: 09 Jun 2021 17:18:43

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:46	11 SEP 2020 10:46
Nasopharyngeal Swab 2	No		

US3372394

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:01

PC Open Date & Time

11 SEP 2020 11:40

PC Close Date & Time

11 SEP 2020 14:10

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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	11 SEP 2020 15:08
PC Open Date & Time	11 SEP 2020 15:05
PC Close Date & Time	12 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:13

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

14 SEP 2020 17:25

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

97.2 °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

15 SEP 2020 18:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

16 SEP 2020 17:16

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 16:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 11:40

PC Close Date & Time

11 SEP 2020 14:10

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

11 SEP 2020 15:09

PC Open Date & Time

11 SEP 2020 15:05

PC Close Date & Time

12 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

12 SEP 2020 18:14

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

13 SEP 2020 12:08

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

14 SEP 2020 17:26

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

15 SEP 2020 18:28

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

16 SEP 2020 17:17

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

17 SEP 2020 16:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 12:03
PC Open Date & Time	11 SEP 2020 11:40
PC Close Date & Time	11 SEP 2020 14:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:10
PC Open Date & Time	11 SEP 2020 15:05
PC Close Date & Time	12 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:14
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2548

EAB) (1725)

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:26
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2548

EAB) (1725)

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:29
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

65 of 2548

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:34
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

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)	09 OCT 2020
Time of assessment (00:00-23:59)	09:49 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:49
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 11:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3372394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

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.

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

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) 09 OCT 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 10:41

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

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	09 OCT 2020 10:15

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:30:23

Generated On: 09 Jun 2021 17:18:43

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:13	09 OCT 2020 10:13
Nasopharyngeal Swab 2	No		

US3372394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:30:58

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 11:15

PC Open Date & Time

09 OCT 2020 11:01

PC Close Date & Time

09 OCT 2020 13:31

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 98.8 °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	09 OCT 2020 18:51
PC Open Date & Time	09 OCT 2020 14:26
PC Close Date & Time	10 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 17:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 17:16

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

98.6 °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

12 OCT 2020 17:50

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

13 OCT 2020 20:54

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

14 OCT 2020 15:16

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

15 OCT 2020 15:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 11:16

PC Open Date & Time

09 OCT 2020 11:01

PC Close Date & Time

09 OCT 2020 13:31

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

09 OCT 2020 18:52

PC Open Date & Time

09 OCT 2020 14:26

PC Close Date & Time

10 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

10 OCT 2020 17:28

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

11 OCT 2020 17:17

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

12 OCT 2020 17:51

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

13 OCT 2020 20:55

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

14 OCT 2020 15:16

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

15 OCT 2020 15:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 11:16
PC Open Date & Time	09 OCT 2020 11:01
PC Close Date & Time	09 OCT 2020 13:31

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 18:52
PC Open Date & Time	09 OCT 2020 14:26
PC Close Date & Time	10 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 17:28
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 17:51
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

109 of 2548

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 20:55
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

111 of 2548

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 15:16
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 15:22
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 22:55:28

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:11:28

Generated On: 09 Jun 2021 17:18:43

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) _____

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:11:28

Generated On: 09 Jun 2021 17:18:43

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.

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:11:28

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	6 NOV 2020 09:30

US3372394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:11:28

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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 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	14 NOV 2020 11:28:25
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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 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"/>

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 16:04:14

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 18:01:49
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 16:43:50
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	24 DEC 2020 23:59
---	-------------------

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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 ☒

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 DEC 2020 08:11:43

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 00:03:40

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 13:28:04

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 08:15:32

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	31 JAN 2021 08:55:39
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 13:49:43

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

14 FEB 2021 10:19:18

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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	22 FEB 2021 18:09:16
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 14:28:40

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 11:02:05

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

14 MAR 2021 00:08:12

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 19:45:35

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 07:46:24
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 23:57:48

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 10:33:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 17:27:34

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 MAY 2021 00:39:28
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	09 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2022 00:01
Patient Cloud Close Date & Time	03 NOV 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3372394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:18:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 14:28:50

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:46:04

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:50:48

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:32:15

Generated On: 09 Jun 2021 17:18:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3372394

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:32:15

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 15:56:05

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 15:56:05

Generated On: 09 Jun 2021 17:18:43

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) _____

US3372394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 15:55:45

Generated On: 09 Jun 2021 17:18:43

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.

US3372394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 15:55:45

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 APR 2021
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	08 APR 2021 10:25

US3372394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 15:55:45

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Date of Contact	01 FEB 2021
Time of Contact	09:30
Date and Time of Contact (derived)	01 FEB 2021 09:30
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input 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>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	02 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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 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

EAB) (1725)

335 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 type="checkbox"/>
Day 9	<input checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	03 FEB 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.3 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

EAB) (1725)

339 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	04 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 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		343 of 2548
EAB) (1725)		

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	05 FEB 2021
------	-------------

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

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

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

Temperature	96.8 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

EAB) (1725)

347 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	06 FEB 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 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
EAB) (1725)

351 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 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 checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	07 FEB 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.9 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

EAB) (1725)

355 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 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 checked="" 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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	08 FEB 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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 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

EAB) (1725)

359 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	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 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

EAB) (1725)

363 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	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 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
EAB) (1725)

367 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	29 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 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

EAB) (1725)

375 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	30 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 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
EAB) (1725)

379 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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 ☐

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	31 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 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
EAB) (1725)

383 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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	01 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.2 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 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
EAB) (1725)

387 of 2548

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

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"/>

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Date of Visit	01 FEB 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	02 FEB 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

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 FEB 2021
Day 5	Yes	06 FEB 2021
Day 7	Yes	08 FEB 2021
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3372394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 09:45
Height (xxx.x)	161.3 cm
Weight (xxx.x)	84.4 kg
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:35:27

Generated On: 09 Jun 2021 17:18:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 FEB 2021

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

US3372394

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 FEB 2021

US3372394

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:23:14

Generated On: 09 Jun 2021 17:18:43

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

Visit date (dd MMM yyyy)	11 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
------------	---------------

US3372394

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 19:32:15

Generated On: 09 Jun 2021 17:18:43

Date of updated informed consent (dd MMM yyyy) 11 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3372394

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:12:58

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

15:11 (24 HR)

Collection date and time (derived)

11 JAN 2021 15:11

US3372394

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:52:25

Generated On: 09 Jun 2021 17:18:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	15:08
Collection Date and Time (derived)	11 JAN 2021 15:08

US3372394

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:56:29

Generated On: 09 Jun 2021 17:18:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:50:31

Generated On: 09 Jun 2021 17:18:43

AEID	USA-US056-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC ATHEROSCLEROTIC DISEASE.
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	402 of 2548

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:50:31

Generated On: 09 Jun 2021 17:18:43

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

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:50:31

Generated On: 09 Jun 2021 17:18:43

SUBJECT US3372394. PHONE
CALL 16 NOVEMBER 2020. 10:10
HOURS. FOLLOW-UP SAFETY
ALERT.

SUBJECT US3372394 WAS
HOSPITALIZED AT CLEVELAND
CLINIC VERO BEACH INDIAN
RIVER FROM 11 NOVEMBER
2020 TILL 13 NOVEMBER 2020
WITH A DIAGNOSIS OF
SYMPTOMATIC
ATHEROSCLEROTIC DISEASE.
SHE IS ASYMPTOMATIC.

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

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:54:29

Generated On: 09 Jun 2021 17:18:43

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

Yes ☒

No ☐

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

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

408 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 2500

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

412 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

414 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication CINNAMON SUPPLEMENT

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

416 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

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)

418 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 AUG 2020
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"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
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

420 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)	26 APR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 APR 2018
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"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
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)

422 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)	22 MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAY 2018
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"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
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)

424 of 2548

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)	11 AUG 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 AUG 2018	
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"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE IIQ

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

426 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)		05 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

428 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 75

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

430 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Name of Medication REGULAR INSULIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

432 of 2548

EAB) (1725)

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Mar 2021 21:48:00

Generated On: 09 Jun 2021 17:18:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Mar 2021 19:32:14

Generated On: 09 Jun 2021 17:18:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 NOV 2020	CAT SCAN HEAD	Diagnostic	
11 NOV 2020	MRI BRAIN	Diagnostic	

US3372394

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:18:43

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3372394

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:18:43

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 15:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/MAR/2021 14:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 27 Apr 2021 01:42:07

Generated On: 09 Jun 2021 17:18:43

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 10:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3372394 (Prod: Palm Beach Research Center)

US3372394

Form: Participant Creation

Generated On: 09 Jun 2021 17:18:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:53:08
User entered 'US3372394'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:29:42

US3372394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 22:09:07
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 23:29:10
' answered with 'data updated ' (Site from DM).		
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:53:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:12:08

US3372394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:29:43

US3372394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:08

US3372394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'SCRN'	System	11 Sep 2020 15:12:08

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:29:44

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'YEARS'	System	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '68'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:18:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:19:07
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Sep 2020'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2020'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:36:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:29:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:18:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'I'	System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:29:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:18:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:01:05
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:47:20

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:54
Data point term sent to Coder	System	28 Sep 2020 21:48:43
User entered 'diabetes mellitus type II'	Peter Jacob (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2008'	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2008'	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:51
Data point term sent to Coder	System	28 Sep 2020 21:48:43
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2005'	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2005'	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:49:55
Data point term sent to Coder	System	28 Sep 2020 21:48:43
User entered 'hypertension'	Peter Jacob (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2010'	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2010'	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:50:46
Data point term sent to Coder	System	28 Sep 2020 21:49:44
User entered 'cholelithiasis'	Peter Jacob (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1976'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1976'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:50:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:50:43
Data point term sent to Coder	System	28 Sep 2020 21:49:51
User entered 'cholecystectomy'	Peter Jacob (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1976'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1976'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Fallopian tube operation, LLT: Fallopian tube operation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:56:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:56:50
Data point term sent to Coder	System	28 Sep 2020 21:49:44
User entered 'fallopian tube fimbriae fusion'	Peter Jacob (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Fallopian tube operation, LLT: Fallopian tube operation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 08:31:56
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 08:31:56
Data point term sent to Coder	System	28 Sep 2020 21:50:51
User entered 'bilateral cuff tuboplasty'	Peter Jacob (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Fractured wrist - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:52:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:52:54
Data point term sent to Coder	System	28 Sep 2020 21:51:54
User entered 'fractured right wrist'	Peter Jacob (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: External fixation of fracture, LLT: External fixation of fracture - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 09:44:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 09:44:00
Data point term sent to Coder	System	28 Sep 2020 21:52:55
User entered 'surgical reduction of wrist fracture with external fixator'	Peter Jacob (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:01:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:01:53
Data point term sent to Coder	System	28 Sep 2020 21:52:55
User entered 'total hip replacement left'	Peter Jacob (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:38:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:37:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:37:02
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:35:38
Data point term sent to Coder	System	20 Nov 2020 19:35:30
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:35:30
User entered 'osteoARTHRITIS OF LEFT HIP' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:35:30
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:52:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:15:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:15:51

PRODUCTION RELEASE (v12.003
EAB) (1725)

575 of 2548

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	28 Sep 2020 21:52:55
User entered 'arthritis of left hip'	Peter Jacob (b) (4)	28 Sep 2020 21:52:45
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:54:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:54:42
Data point term sent to Coder	System	28 Sep 2020 21:53:55
User entered 'total hip replacement right'	Peter Jacob (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:38:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:52:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:52:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:37:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 19:37:02
Data point term sent to Coder	System	20 Nov 2020 19:36:32
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:36:08
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:35:58
User entered 'osteoARTHRITIS RIGHT HIP' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 19:35:58
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:53:24

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:54:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:54:42
Data point term sent to Coder	System	28 Sep 2020 21:53:56
User entered 'arthritis right hip'	Peter Jacob (b) (4)	28 Sep 2020 21:53:39
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Female reproductive tract infections, PT: Pelvic inflammatory disease, LLT: Pelvic inflammatory disease - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
Data point term sent to Coder	System	28 Sep 2020 21:54:58
User entered 'pelvic inflammatory disease'	Peter Jacob (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1979'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1979'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
Data point term sent to Coder	System	28 Sep 2020 21:54:57
User entered 'postmenopausal'	Peter Jacob (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'un UNK 1998'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:45:28
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'Jan 1998'	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '1998'	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered '10:21'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '11 Sep 2020 10:21'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered '161.3' cm	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:36:24
DataPoint set to visible.	(b) (4) System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered '85.6' kg	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:36:24
DataPoint set to visible.	(b) (4) System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '32.90069'	System	18 Sep 2020 18:36:24
DataPoint set to visible.	System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'kg/m2'	System	18 Sep 2020 18:36:24
DataPoint set to visible.	System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
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) (b) (4), (b) (6)	28 Sep 2020 07:57:56
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 'done' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:12:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:11:59
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), (b) (6)	25 Sep 2020 12:07:58
User entered '36.6' C	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered 'Oral (Oral)'	(b) (4)	
	Peter Jacob (b) (4)	18 Sep 2020 18:36:24
	(b) (4)	

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:59
User entered '71'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24
	(b) (4)	

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'bpm'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:59
User entered '16'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24
	(b) (4)	

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'breaths/min'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:59
User entered '127'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24
	(b) (4)	

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'mmHg'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:39:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:59
User entered '84'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24
	(b) (4)	

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'mmHg'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29

US3372394

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:16:56
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:36:41

US3372394

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:16:56
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:41

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered 'un UNK 1998'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:18:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:05:35
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'No (N)'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'retired'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	Peter Jacob (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:18:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:27:13
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'VISIT1'	System	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered '190576'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:11:28
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 21:59:14
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:07:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:18

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
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)	28 Sep 2020 07:41:56
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.' answered with 'done' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 16:55:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 16:54:36
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)	25 Sep 2020 12:07:48
User entered '161.3' cm	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
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)	28 Sep 2020 07:41:56
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)	25 Sep 2020 16:55:46
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 16:54:36
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)	25 Sep 2020 12:07:48
User entered '161.3' cm	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '10:21'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '11 Sep 2020 10:21'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '71'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'bpm'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'breaths/min'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '127'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '84'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
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)	28 Sep 2020 07:41:56
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.' answered with 'done' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 16:55:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 16:54:36
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)	25 Sep 2020 12:07:48
User entered '161.3' cm	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:18:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '11:55'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '11 Sep 2020 11:55'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '75'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'bpm'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'breaths/min'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '110'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:55:34
User entered '68'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:16:56
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:39:55

US3372394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:16:56
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:55

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered '11:20'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '11 Sep 2020 11:20'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:54:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'ONCE'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered '10:50'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '11 Sep 2020 10:50'	System	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered '11 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered '10:46'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '11 Sep 2020 10:46'	System	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:28

US3372394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '1'	System	18 Sep 2020 18:40:28

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:01:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'cda9e141-0497-4537-a910-72bf7bc050b0'	System	11 Sep 2020 16:04:39
User entered 'Yes (Y)'	System	11 Sep 2020 16:04:39

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:01:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'cda9e141-0497-4537-a910-72bf7bc050b0' User entered '97.9'	System	11 Sep 2020 16:04:39
	System	11 Sep 2020 16:04:39

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:01:34', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'cda9e141-0497-4537-a910-72bf7bc050b0'	System	11 Sep 2020 16:04:39
User entered 'No (N)'	System	11 Sep 2020 16:04:39

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:01:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'cda9e141-0497-4537-a910-72bf7bc050b0'	System	11 Sep 2020 16:04:39
User entered '11 Sep 2020 12:01'	System	11 Sep 2020 16:04:39

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 11:40'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 14:10'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:07:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6a53d388-e3dc-4c48-9053-233b61ba4196'	System	11 Sep 2020 19:08:08
User entered 'Yes (Y)'	System	11 Sep 2020 19:08:08

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:07:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6a53d388-e3dc-4c48-9053-233b61ba4196'	System	11 Sep 2020 19:08:08
User entered '98.2'	System	11 Sep 2020 19:08:08

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:07:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6a53d388-e3dc-4c48-9053-233b61ba4196'	System	11 Sep 2020 19:08:08
User entered 'No (N)'	System	11 Sep 2020 19:08:08

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:08:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6a53d388-e3dc-4c48-9053-233b61ba4196'	System	11 Sep 2020 19:08:08
User entered '11 Sep 2020 15:08'	System	11 Sep 2020 19:08:08

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 15:05'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 2'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '48667b63-acde-4884-b50a-03d72404efa1'	System	12 Sep 2020 22:13:40
User entered 'Yes (Y)'	System	12 Sep 2020 22:13:40

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '48667b63-acde-4884-b50a-03d72404efa1'	System	12 Sep 2020 22:13:40
User entered '98.0'	System	12 Sep 2020 22:13:40

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:30', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '48667b63-acde-4884-b50a-03d72404efa1'	System	12 Sep 2020 22:13:40
User entered 'No (N)'	System	12 Sep 2020 22:13:40

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:36', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '48667b63-acde-4884-b50a-03d72404efa1'	System	12 Sep 2020 22:13:40
User entered '12 Sep 2020 18:13'	System	12 Sep 2020 22:13:40

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 3'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:30', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3ca34531-8863-410f-a6c5-c8b042e7dba9'	System	13 Sep 2020 16:07:48
User entered 'Yes (Y)'	System	13 Sep 2020 16:07:48

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3ca34531-8863-410f-a6c5-c8b042e7dba9'	System	13 Sep 2020 16:07:48
User entered '97.4'	System	13 Sep 2020 16:07:48

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3ca34531-8863-410f-a6c5-c8b042e7dba9'	System	13 Sep 2020 16:07:48
User entered 'No (N)'	System	13 Sep 2020 16:07:48

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:47', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3ca34531-8863-410f-a6c5-c8b042e7dba9'	System	13 Sep 2020 16:07:48
User entered '13 Sep 2020 12:07'	System	13 Sep 2020 16:07:48

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 4'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1cc06174-284d-488e-8c19-de503c275b2d'	System	14 Sep 2020 21:25:41
User entered 'Yes (Y)'	System	14 Sep 2020 21:25:41

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1cc06174-284d-488e-8c19-de503c275b2d'	System	14 Sep 2020 21:25:41
User entered '97.5'	System	14 Sep 2020 21:25:41

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1cc06174-284d-488e-8c19-de503c275b2d'	System	14 Sep 2020 21:25:41
User entered 'No (N)'	System	14 Sep 2020 21:25:41

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1cc06174-284d-488e-8c19-de503c275b2d'	System	14 Sep 2020 21:25:41
User entered '14 Sep 2020 17:25'	System	14 Sep 2020 21:25:41

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 5'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:27:44', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba53133f-5b3b-4412-bd00-41e2eaa8d754'	System	15 Sep 2020 22:28:01
User entered 'Yes (Y)'	System	15 Sep 2020 22:28:01

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:27:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba53133f-5b3b-4412-bd00-41e2eaa8d754'	System	15 Sep 2020 22:28:01
User entered '97.2'	System	15 Sep 2020 22:28:01

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:27:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba53133f-5b3b-4412-bd00-41e2eaa8d754'	System	15 Sep 2020 22:28:01
User entered 'No (N)'	System	15 Sep 2020 22:28:01

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:27:59', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba53133f-5b3b-4412-bd00-41e2eaa8d754'	System	15 Sep 2020 22:28:01
User entered '15 Sep 2020 18:27'	System	15 Sep 2020 22:28:01

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 6'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:29', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c0c67a9d-3871-4713-a208-1b8f58265ba7'	System	16 Sep 2020 21:16:51
User entered 'Yes (Y)'	System	16 Sep 2020 21:16:51

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c0c67a9d-3871-4713-a208-1b8f58265ba7' User entered '97.4'	System	16 Sep 2020 21:16:51
	System	16 Sep 2020 21:16:51

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:38', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c0c67a9d-3871-4713-a208-1b8f58265ba7'	System	16 Sep 2020 21:16:51
User entered 'No (N)'	System	16 Sep 2020 21:16:51

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:44', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c0c67a9d-3871-4713-a208-1b8f58265ba7'	System	16 Sep 2020 21:16:51
User entered '16 Sep 2020 17:16'	System	16 Sep 2020 21:16:51

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 7'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:32:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9f79de88-c3b6-487c-9623-85234bb9e0ad'	System	17 Sep 2020 20:33:16
User entered 'Yes (Y)'	System	17 Sep 2020 20:33:16

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9f79de88-c3b6-487c-9623-85234bb9e0ad' User entered '97.0'	System	17 Sep 2020 20:33:16
	System	17 Sep 2020 20:33:16

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:03', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9f79de88-c3b6-487c-9623-85234bb9e0ad'	System	17 Sep 2020 20:33:16
User entered 'No (N)'	System	17 Sep 2020 20:33:16

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9f79de88-c3b6-487c-9623-85234bb9e0ad'	System	17 Sep 2020 20:33:16
User entered '17 Sep 2020 16:33'	System	17 Sep 2020 20:33:16

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:02:47', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '36f665f8-4e0f-49f2-8c03-67947d01a8b1'	System	11 Sep 2020 16:06:01
User entered 'None (1)'	System	11 Sep 2020 16:06:01

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:02:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '36f665f8-4e0f-49f2-8c03-67947d01a8b1'	System	11 Sep 2020 16:06:01
User entered 'No (N)'	System	11 Sep 2020 16:06:01

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:02:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '36f665f8-4e0f-49f2-8c03-67947d01a8b1'	System	11 Sep 2020 16:06:01
User entered 'No (N)'	System	11 Sep 2020 16:06:01

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:02:58', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '36f665f8-4e0f-49f2-8c03-67947d01a8b1'	System	11 Sep 2020 16:06:01
User entered 'None (1)'	System	11 Sep 2020 16:06:01

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '36f665f8-4e0f-49f2-8c03-67947d01a8b1'	System	11 Sep 2020 16:06:01
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:01

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 11:40'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 14:10'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:08:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5de07d11-ebb9-4983-8d07-a987d700060a'	System	11 Sep 2020 19:09:45
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:09:45

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5de07d11-ebb9-4983-8d07-a987d700060a'	System	11 Sep 2020 19:09:45
User entered 'No (N)'	System	11 Sep 2020 19:09:45

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:03', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5de07d11-ebb9-4983-8d07-a987d700060a'	System	11 Sep 2020 19:09:45
User entered 'No (N)'	System	11 Sep 2020 19:09:45

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5de07d11-ebb9-4983-8d07-a987d700060a'	System	11 Sep 2020 19:09:45
User entered 'None (1)'	System	11 Sep 2020 19:09:45

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5de07d11-ebb9-4983-8d07-a987d700060a'	System	11 Sep 2020 19:09:45
User entered '11 Sep 2020 15:09'	System	11 Sep 2020 19:09:45

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 15:05'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 2'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec248a2f-cd49-466d-9dc4-05418bdbbf05'	System	12 Sep 2020 22:14:21
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:14:21

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:13:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec248a2f-cd49-466d-9dc4-05418bdbbf05'	System	12 Sep 2020 22:14:21
User entered 'No (N)'	System	12 Sep 2020 22:14:21

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec248a2f-cd49-466d-9dc4-05418bdbbf05'	System	12 Sep 2020 22:14:21
User entered 'No (N)'	System	12 Sep 2020 22:14:21

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:06', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec248a2f-cd49-466d-9dc4-05418bdbbf05'	System	12 Sep 2020 22:14:21
User entered 'None (1)'	System	12 Sep 2020 22:14:21

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:17', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec248a2f-cd49-466d-9dc4-05418bdbbf05'	System	12 Sep 2020 22:14:21
User entered '12 Sep 2020 18:14'	System	12 Sep 2020 22:14:21

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 3'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aa55a5b8-a9b5-48fb-a22f-57541547df70'	System	13 Sep 2020 16:08:15
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 16:08:15

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:07:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aa55a5b8-a9b5-48fb-a22f-57541547df70'	System	13 Sep 2020 16:08:15
User entered 'No (N)'	System	13 Sep 2020 16:08:15

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aa55a5b8-a9b5-48fb-a22f-57541547df70'	System	13 Sep 2020 16:08:15
User entered 'No (N)'	System	13 Sep 2020 16:08:15

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aa55a5b8-a9b5-48fb-a22f-57541547df70'	System	13 Sep 2020 16:08:15
User entered 'None (1)'	System	13 Sep 2020 16:08:15

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aa55a5b8-a9b5-48fb-a22f-57541547df70'	System	13 Sep 2020 16:08:15
User entered '13 Sep 2020 12:08'	System	13 Sep 2020 16:08:15

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 4'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:50', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1d62dd2c-baab-4591-bb43-d20f34dd7621'	System	14 Sep 2020 21:26:09
User entered 'None (1)'	System	14 Sep 2020 21:26:09

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1d62dd2c-baab-4591-bb43-d20f34dd7621'	System	14 Sep 2020 21:26:09
User entered 'No (N)'	System	14 Sep 2020 21:26:09

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:25:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1d62dd2c-baab-4591-bb43-d20f34dd7621'	System	14 Sep 2020 21:26:09
User entered 'No (N)'	System	14 Sep 2020 21:26:09

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1d62dd2c-baab-4591-bb43-d20f34dd7621'	System	14 Sep 2020 21:26:09
User entered 'None (1)'	System	14 Sep 2020 21:26:09

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '1d62dd2c-baab-4591-bb43-d20f34dd7621'	System	14 Sep 2020 21:26:09
User entered '14 Sep 2020 17:26'	System	14 Sep 2020 21:26:09

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 5'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7d4c5642-e151-4ceb-8ae5-23048de61767'	System	15 Sep 2020 22:28:41
User entered 'None (1)'	System	15 Sep 2020 22:28:41

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7d4c5642-e151-4ceb-8ae5-23048de61767'	System	15 Sep 2020 22:28:41
User entered 'No (N)'	System	15 Sep 2020 22:28:41

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7d4c5642-e151-4ceb-8ae5-23048de61767'	System	15 Sep 2020 22:28:41
User entered 'No (N)'	System	15 Sep 2020 22:28:41

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7d4c5642-e151-4ceb-8ae5-23048de61767'	System	15 Sep 2020 22:28:41
User entered 'None (1)'	System	15 Sep 2020 22:28:41

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7d4c5642-e151-4ceb-8ae5-23048de61767'	System	15 Sep 2020 22:28:41
User entered '15 Sep 2020 18:28'	System	15 Sep 2020 22:28:41

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 6'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:48', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'eb84598d-1577-408b-ac73-671f9f936779'	System	16 Sep 2020 21:17:17
User entered 'None (1)'	System	16 Sep 2020 21:17:17

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'eb84598d-1577-408b-ac73-671f9f936779'	System	16 Sep 2020 21:17:17
User entered 'No (N)'	System	16 Sep 2020 21:17:17

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:55', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'eb84598d-1577-408b-ac73-671f9f936779'	System	16 Sep 2020 21:17:17
User entered 'No (N)'	System	16 Sep 2020 21:17:17

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:16:59', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'eb84598d-1577-408b-ac73-671f9f936779'	System	16 Sep 2020 21:17:17
User entered 'None (1)'	System	16 Sep 2020 21:17:17

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'eb84598d-1577-408b-ac73-671f9f936779'	System	16 Sep 2020 21:17:17
User entered '16 Sep 2020 17:17'	System	16 Sep 2020 21:17:17

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 7'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '2ce4eae6-1233-4de1-8262-f9ff249dddb0'	System	17 Sep 2020 20:33:37
User entered 'None (1)'	System	17 Sep 2020 20:33:37

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:19', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '2ce4eae6-1233-4de1-8262-f9ff249dddb0'	System	17 Sep 2020 20:33:37
User entered 'No (N)'	System	17 Sep 2020 20:33:37

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:22', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '2ce4eae6-1233-4de1-8262-f9ff249dddb0'	System	17 Sep 2020 20:33:37
User entered 'No (N)'	System	17 Sep 2020 20:33:37

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '2ce4eae6-1233-4de1-8262-f9ff249dddb0'	System	17 Sep 2020 20:33:37
User entered 'None (1)'	System	17 Sep 2020 20:33:37

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '2ce4eae6-1233-4de1-8262-f9ff249dddb0'	System	17 Sep 2020 20:33:37
User entered '17 Sep 2020 16:33'	System	17 Sep 2020 20:33:37

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:09', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:11', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:17', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:19', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:21', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'None (0)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:27', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered 'No (N)'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T12:03:30', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ed88ffb5-e0cd-4275-ae1b-b9f2cf89fbd8'	System	11 Sep 2020 16:06:25
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:25

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 11:40'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 14:10'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:09:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:01', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'None (0)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered 'No (N)'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-11T15:10:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '3e453af8-e5a7-414a-9aac-9db3bcd0cbea'	System	11 Sep 2020 19:10:29
User entered '11 Sep 2020 15:10'	System	11 Sep 2020 19:10:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Sep 2020 15:05'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 2'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:24', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'None (0)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:48', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered 'No (N)'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-12T18:14:56', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba15de04-31ab-4ca4-83db-f898b3f1408c'	System	12 Sep 2020 22:15:11
User entered '12 Sep 2020 18:14'	System	12 Sep 2020 22:15:11

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 3'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:22', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:29', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:34', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'None (0)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered 'No (N)'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-13T12:08:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ea9a5983-58b0-4b6e-9902-25d4a84e0aeb'	System	13 Sep 2020 16:08:53
User entered '13 Sep 2020 12:08'	System	13 Sep 2020 16:08:53

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 4'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'None (0)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered 'No (N)'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-14T17:26:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '545bb6ff-1fff-4eda-b350-435ffe3354ae'	System	14 Sep 2020 21:26:40
User entered '14 Sep 2020 17:26'	System	14 Sep 2020 21:26:40

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 5'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:44', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:56', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'None (0)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:28:59', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered 'No (N)'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-15T18:29:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '220733fe-97bb-4c4f-a8e1-5e7be4b72ba5'	System	15 Sep 2020 22:29:10
User entered '15 Sep 2020 18:29'	System	15 Sep 2020 22:29:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 6'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:33', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'None (0)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:38', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered 'No (N)'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-16T17:17:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '9d083c63-8bae-4425-96dc-e9dc754593d4'	System	16 Sep 2020 21:17:49
User entered '16 Sep 2020 17:17'	System	16 Sep 2020 21:17:49

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 7'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:38', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:41', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'None (0)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:33:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered 'No (N)'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-09-17T16:34:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '84fe3939-39d9-425f-8fea-39a64d85583e'	System	17 Sep 2020 20:34:10
User entered '17 Sep 2020 16:34'	System	17 Sep 2020 20:34:10

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:30:29

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '18 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:43:26

US3372394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	02 Oct 2020 13:43:26

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Dec 2020 21:42:34

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '25 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Dec 2020 21:42:34

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peter Jacob (b) (4)	04 Dec 2020 21:42:34

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Dec 2020 21:42:34

US3372394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:45:06

US3372394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	02 Oct 2020 13:45:06

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '2 Oct 2020'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	02 Oct 2020 13:49:49

US3372394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	02 Oct 2020 13:49:49

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 15:46:51
User entered '9 Oct 2020'	Peter Jacob (b) (4)	15 Oct 2020 15:46:51
	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'VISIT2'	System	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '09 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '09:49'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '09 Oct 2020 09:49'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '63'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'bpm'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'breaths/min'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '131'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '81'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '09 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '11:16'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '09 Oct 2020 11:16'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '63'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'bpm'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'breaths/min'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '126'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '81'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'mmHg'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:44

US3372394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:44

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4)	16 Oct 2020 15:45:53
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Peter Jacob (b) (4)	15 Oct 2020 15:47:48
' answered with 'data updated' (Site from DM).	(b) (4)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	15 Oct 2020 14:51:06
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4)	15 Oct 2020 14:40:55
' (Site from DM).	(b) (4), (b) (6)	
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '10:41'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '09 Oct 2020 10:41'	System	15 Oct 2020 14:51:06
User entered '9 Oct 2020 10:41'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'ONCE'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:18:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '09 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered '10:15'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '09 Oct 2020 10:15'	System	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered '09 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered '10:13'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '09 Oct 2020 10:13'	System	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:30:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:30:58
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:08

US3372394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '1'	System	15 Oct 2020 15:48:08

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:15:01', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'd16d9bff-ac22-4af2-914d-beddc66d1c4'	System	09 Oct 2020 15:15:55
User entered 'Yes (Y)'	System	09 Oct 2020 15:15:55

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:15:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'd16d9bff-ac22-4af2-914d-beddc66d1c4'	System	09 Oct 2020 15:15:55
User entered '97.9'	System	09 Oct 2020 15:15:55

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:15:22', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'd16d9bff-ac22-4af2-914d-beddc66d1c4'	System	09 Oct 2020 15:15:55
User entered 'No (N)'	System	09 Oct 2020 15:15:55

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:15:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'd16d9bff-ac22-4af2-914d-beddc66d1c4'	System	09 Oct 2020 15:15:55
User entered '09 Oct 2020 11:15'	System	09 Oct 2020 15:15:55

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 11:01'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 13:31'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:50:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '8fc30a9a-c3a9-4e18-9a7f-2c9137a5b570'	System	09 Oct 2020 22:51:20
User entered 'Yes (Y)'	System	09 Oct 2020 22:51:20

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:05', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '8fc30a9a-c3a9-4e18-9a7f-2c9137a5b570'	System	09 Oct 2020 22:51:20
User entered '98.8'	System	09 Oct 2020 22:51:20

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:09', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '8fc30a9a-c3a9-4e18-9a7f-2c9137a5b570'	System	09 Oct 2020 22:51:20
User entered 'No (N)'	System	09 Oct 2020 22:51:20

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:17', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '8fc30a9a-c3a9-4e18-9a7f-2c9137a5b570'	System	09 Oct 2020 22:51:20
User entered '09 Oct 2020 18:51'	System	09 Oct 2020 22:51:20

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 14:26'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 2'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'b0389d90-3082-4561-9fd2-9c58d5bcd9c9'	System	10 Oct 2020 21:27:39
User entered 'Yes (Y)'	System	10 Oct 2020 21:27:39

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'b0389d90-3082-4561-9fd2-9c58d5bcd9c9' User entered '99.9'	System	10 Oct 2020 21:27:39
	System	10 Oct 2020 21:27:39

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'b0389d90-3082-4561-9fd2-9c58d5bcd9c9'	System	10 Oct 2020 21:27:39
User entered 'No (N)'	System	10 Oct 2020 21:27:39

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:36', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'b0389d90-3082-4561-9fd2-9c58d5bcd9c9'	System	10 Oct 2020 21:27:39
User entered '10 Oct 2020 17:27'	System	10 Oct 2020 21:27:39

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 3'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '542f9d22-1e50-4e3c-bc32-ee8eec60db81'	System	11 Oct 2020 21:16:51
User entered 'Yes (Y)'	System	11 Oct 2020 21:16:51

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '542f9d22-1e50-4e3c-bc32-ee8eec60db81'	System	11 Oct 2020 21:16:51
User entered '98.3'	System	11 Oct 2020 21:16:51

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '542f9d22-1e50-4e3c-bc32-ee8eec60db81'	System	11 Oct 2020 21:16:51
User entered 'No (N)'	System	11 Oct 2020 21:16:51

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:47', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '542f9d22-1e50-4e3c-bc32-ee8eec60db81'	System	11 Oct 2020 21:16:51
User entered '11 Oct 2020 17:16'	System	11 Oct 2020 21:16:51

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 4'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '04346218-6cf6-4e6a-955d-b4548e192cb5'	System	12 Oct 2020 21:50:44
User entered 'Yes (Y)'	System	12 Oct 2020 21:50:44

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '04346218-6cf6-4e6a-955d-b4548e192cb5'	System	12 Oct 2020 21:50:44
User entered '98.6'	System	12 Oct 2020 21:50:44

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '04346218-6cf6-4e6a-955d-b4548e192cb5'	System	12 Oct 2020 21:50:44
User entered 'No (N)'	System	12 Oct 2020 21:50:44

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:41', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '04346218-6cf6-4e6a-955d-b4548e192cb5'	System	12 Oct 2020 21:50:44
User entered '12 Oct 2020 17:50'	System	12 Oct 2020 21:50:44

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 5'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:53:47', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ffc8cf2a-2604-43a9-9c44-c41c355e7fdc'	System	14 Oct 2020 00:54:10
User entered 'Yes (Y)'	System	14 Oct 2020 00:54:10

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:53:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ffc8cf2a-2604-43a9-9c44-c41c355e7fdc'	System	14 Oct 2020 00:54:10
User entered '98.7'	System	14 Oct 2020 00:54:10

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:53:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ffc8cf2a-2604-43a9-9c44-c41c355e7fdc'	System	14 Oct 2020 00:54:10
User entered 'No (N)'	System	14 Oct 2020 00:54:10

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:54:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ffc8cf2a-2604-43a9-9c44-c41c355e7fdc'	System	14 Oct 2020 00:54:10
User entered '13 Oct 2020 20:54'	System	14 Oct 2020 00:54:10

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 6'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:15:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7b589222-52a3-4a82-a6c8-ef05dcdf20b8'	System	14 Oct 2020 19:16:06
User entered 'Yes (Y)'	System	14 Oct 2020 19:16:06

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:15:52', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7b589222-52a3-4a82-a6c8-ef05dcaf20b8'	System	14 Oct 2020 19:16:06
User entered '98.4'	System	14 Oct 2020 19:16:06

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:15:55', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7b589222-52a3-4a82-a6c8-ef05dcaf20b8'	System	14 Oct 2020 19:16:06
User entered 'No (N)'	System	14 Oct 2020 19:16:06

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7b589222-52a3-4a82-a6c8-ef05dcdf20b8'	System	14 Oct 2020 19:16:06
User entered '14 Oct 2020 15:16'	System	14 Oct 2020 19:16:06

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 7'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '01b50a4e-0f75-48b7-8aa9-43936ca76c9d'	System	15 Oct 2020 19:21:33
User entered 'Yes (Y)'	System	15 Oct 2020 19:21:33

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:21', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '01b50a4e-0f75-48b7-8aa9-43936ca76c9d'	System	15 Oct 2020 19:21:33
User entered '98.5'	System	15 Oct 2020 19:21:33

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:24', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '01b50a4e-0f75-48b7-8aa9-43936ca76c9d'	System	15 Oct 2020 19:21:33
User entered 'No (N)'	System	15 Oct 2020 19:21:33

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '01b50a4e-0f75-48b7-8aa9-43936ca76c9d'	System	15 Oct 2020 19:21:33
User entered '15 Oct 2020 15:21'	System	15 Oct 2020 19:21:33

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '65e5012e-fd34-4f27-a32d-b2b3a71d63b2'	System	09 Oct 2020 15:16:29
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 15:16:29

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '65e5012e-fd34-4f27-a32d-b2b3a71d63b2'	System	09 Oct 2020 15:16:29
User entered 'No (N)'	System	09 Oct 2020 15:16:29

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '65e5012e-fd34-4f27-a32d-b2b3a71d63b2'	System	09 Oct 2020 15:16:29
User entered 'No (N)'	System	09 Oct 2020 15:16:29

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:19', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '65e5012e-fd34-4f27-a32d-b2b3a71d63b2'	System	09 Oct 2020 15:16:29
User entered 'None (1)'	System	09 Oct 2020 15:16:29

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '65e5012e-fd34-4f27-a32d-b2b3a71d63b2'	System	09 Oct 2020 15:16:29
User entered '09 Oct 2020 11:16'	System	09 Oct 2020 15:16:29

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 11:01'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 13:31'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:24', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5db1d7bb-adb8-4cf3-823c-4cdf45ab6573'	System	09 Oct 2020 22:52:13
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 22:52:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5db1d7bb-adb8-4cf3-823c-4cdf45ab6573'	System	09 Oct 2020 22:52:13
User entered 'No (N)'	System	09 Oct 2020 22:52:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:51:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5db1d7bb-adb8-4cf3-823c-4cdf45ab6573'	System	09 Oct 2020 22:52:13
User entered 'No (N)'	System	09 Oct 2020 22:52:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5db1d7bb-adb8-4cf3-823c-4cdf45ab6573'	System	09 Oct 2020 22:52:13
User entered 'None (1)'	System	09 Oct 2020 22:52:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5db1d7bb-adb8-4cf3-823c-4cdf45ab6573'	System	09 Oct 2020 22:52:13
User entered '09 Oct 2020 18:52'	System	09 Oct 2020 22:52:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 14:26'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 2'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5f325138-6b85-4ab4-adf0-6dde0ef2d934'	System	10 Oct 2020 21:28:13
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 21:28:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:46', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5f325138-6b85-4ab4-adf0-6dde0ef2d934'	System	10 Oct 2020 21:28:13
User entered 'No (N)'	System	10 Oct 2020 21:28:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5f325138-6b85-4ab4-adf0-6dde0ef2d934'	System	10 Oct 2020 21:28:13
User entered 'No (N)'	System	10 Oct 2020 21:28:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:27:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5f325138-6b85-4ab4-adf0-6dde0ef2d934'	System	10 Oct 2020 21:28:13
User entered 'None (1)'	System	10 Oct 2020 21:28:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:11', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5f325138-6b85-4ab4-adf0-6dde0ef2d934'	System	10 Oct 2020 21:28:13
User entered '10 Oct 2020 17:28'	System	10 Oct 2020 21:28:13

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 3'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ff63fb36-b71d-4c9c-b667-0806977a803c'	System	11 Oct 2020 21:17:14
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 21:17:14

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:56', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ff63fb36-b71d-4c9c-b667-0806977a803c'	System	11 Oct 2020 21:17:14
User entered 'No (N)'	System	11 Oct 2020 21:17:14

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:16:58', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ff63fb36-b71d-4c9c-b667-0806977a803c'	System	11 Oct 2020 21:17:14
User entered 'No (N)'	System	11 Oct 2020 21:17:14

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:01', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ff63fb36-b71d-4c9c-b667-0806977a803c'	System	11 Oct 2020 21:17:14
User entered 'None (1)'	System	11 Oct 2020 21:17:14

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ff63fb36-b71d-4c9c-b667-0806977a803c'	System	11 Oct 2020 21:17:14
User entered '11 Oct 2020 17:17'	System	11 Oct 2020 21:17:14

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 4'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:50', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'df069849-0bd8-4b3a-b6ab-b7948f445754'	System	12 Oct 2020 21:51:12
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 21:51:12

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'df069849-0bd8-4b3a-b6ab-b7948f445754'	System	12 Oct 2020 21:51:12
User entered 'No (N)'	System	12 Oct 2020 21:51:12

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:50:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'df069849-0bd8-4b3a-b6ab-b7948f445754'	System	12 Oct 2020 21:51:12
User entered 'No (N)'	System	12 Oct 2020 21:51:12

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'df069849-0bd8-4b3a-b6ab-b7948f445754'	System	12 Oct 2020 21:51:12
User entered 'None (1)'	System	12 Oct 2020 21:51:12

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:08', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'df069849-0bd8-4b3a-b6ab-b7948f445754'	System	12 Oct 2020 21:51:12
User entered '12 Oct 2020 17:51'	System	12 Oct 2020 21:51:12

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 5'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:54:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'dfb42176-de44-4738-af33-05dc2e6ebb07'	System	14 Oct 2020 00:55:27
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 00:55:27

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:54:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'dfb42176-de44-4738-af33-05dc2e6ebb07'	System	14 Oct 2020 00:55:27
User entered 'No (N)'	System	14 Oct 2020 00:55:27

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'dfb42176-de44-4738-af33-05dc2e6ebb07'	System	14 Oct 2020 00:55:27
User entered 'No (N)'	System	14 Oct 2020 00:55:27

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:17', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'dfb42176-de44-4738-af33-05dc2e6ebb07'	System	14 Oct 2020 00:55:27
User entered 'None (1)'	System	14 Oct 2020 00:55:27

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:24', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'dfb42176-de44-4738-af33-05dc2e6ebb07'	System	14 Oct 2020 00:55:27
User entered '13 Oct 2020 20:55'	System	14 Oct 2020 00:55:27

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 6'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '76c45bec-8d38-4a59-9c79-c10913141df0'	System	14 Oct 2020 19:16:32
User entered 'None (1)'	System	14 Oct 2020 19:16:32

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:10', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '76c45bec-8d38-4a59-9c79-c10913141df0'	System	14 Oct 2020 19:16:32
User entered 'No (N)'	System	14 Oct 2020 19:16:32

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '76c45bec-8d38-4a59-9c79-c10913141df0'	System	14 Oct 2020 19:16:32
User entered 'No (N)'	System	14 Oct 2020 19:16:32

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '76c45bec-8d38-4a59-9c79-c10913141df0'	System	14 Oct 2020 19:16:32
User entered 'None (1)'	System	14 Oct 2020 19:16:32

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '76c45bec-8d38-4a59-9c79-c10913141df0'	System	14 Oct 2020 19:16:32
User entered '14 Oct 2020 15:16'	System	14 Oct 2020 19:16:32

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 7'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:34', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '0d555649-ae47-4391-9595-531b5fa4b84b'	System	15 Oct 2020 19:21:54
User entered 'None (1)'	System	15 Oct 2020 19:21:54

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '0d555649-ae47-4391-9595-531b5fa4b84b'	System	15 Oct 2020 19:21:54
User entered 'No (N)'	System	15 Oct 2020 19:21:54

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '0d555649-ae47-4391-9595-531b5fa4b84b'	System	15 Oct 2020 19:21:54
User entered 'No (N)'	System	15 Oct 2020 19:21:54

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:44', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '0d555649-ae47-4391-9595-531b5fa4b84b'	System	15 Oct 2020 19:21:54
User entered 'None (1)'	System	15 Oct 2020 19:21:54

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '0d555649-ae47-4391-9595-531b5fa4b84b'	System	15 Oct 2020 19:21:54
User entered '15 Oct 2020 15:21'	System	15 Oct 2020 19:21:54

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:38', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'None (0)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:48', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered 'No (N)'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T11:16:51', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ade9f2fc-1ef7-4222-a296-f8a90a628e05'	System	09 Oct 2020 15:16:56
User entered '09 Oct 2020 11:16'	System	09 Oct 2020 15:16:56

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 11:01'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 13:31'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636eddd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636eddd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636edd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:26', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636eddd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:29', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636eddd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636eddd6ac'	System	09 Oct 2020 22:52:46
User entered 'None (0)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636edd6ac'	System	09 Oct 2020 22:52:46
User entered 'No (N)'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-09T18:52:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '73d573d5-728a-4675-84d5-324636edd6ac'	System	09 Oct 2020 22:52:46
User entered '09 Oct 2020 18:52'	System	09 Oct 2020 22:52:46

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '09 Oct 2020 14:26'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 2'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:17', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:29', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:33', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:36', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'None (0)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered 'No (N)'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-10T17:28:58', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'f781256f-cda3-427f-a352-745d31ee98a7'	System	10 Oct 2020 21:29:03
User entered '10 Oct 2020 17:28'	System	10 Oct 2020 21:29:03

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 3'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'None (0)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered 'No (N)'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-11T17:17:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '85fe221f-8bf0-4a8a-b046-dbda85705236'	System	11 Oct 2020 21:17:44
User entered '11 Oct 2020 17:17'	System	11 Oct 2020 21:17:44

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 4'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:19', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:22', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:29', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'None (0)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered 'No (N)'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-12T17:51:57', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'aeb6f07d-daea-433c-8ef9-5bd68a6303b0'	System	12 Oct 2020 21:51:59
User entered '12 Oct 2020 17:51'	System	12 Oct 2020 21:51:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 5'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:30', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:33', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:36', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'None (0)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:47', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered 'No (N)'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-13T20:55:55', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'deca700f-a6c1-4257-93ec-51c28c32a224'	System	14 Oct 2020 00:56:01
User entered '13 Oct 2020 20:55'	System	14 Oct 2020 00:56:01

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 6'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:31', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:34', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:42', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:45', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'None (0)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:48', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered 'No (N)'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-14T15:16:53', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '010933b9-1f05-4fb5-a2f9-5b5fb5b30171'	System	14 Oct 2020 19:16:59
User entered '14 Oct 2020 15:16'	System	14 Oct 2020 19:16:59

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	09 Oct 2020 14:43:21
User entered 'Day 7'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:56', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:21:59', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:09', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'None (0)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:12', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered 'No (N)'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-10-15T15:22:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '19a17fce-2e8f-4eed-9bd5-2ebb7830df4d'	System	15 Oct 2020 19:22:23
User entered '15 Oct 2020 15:22'	System	15 Oct 2020 19:22:23

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:43:21

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:18:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:43:21

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Oct 2020 19:23:23

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '16 Oct 2020'	(b) (4) Danielle Theodore (b) (4)	16 Oct 2020 19:23:23
	(b) (4)	

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	16 Oct 2020 19:23:23
	(b) (4)	

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Oct 2020 19:23:23

US3372394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	16 Oct 2020 19:23:29
	(b) (4)	

US3372394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	16 Oct 2020 19:23:29

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	23 Oct 2020 19:02:27

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '23 Oct 2020'	(b) (4) Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	23 Oct 2020 19:02:27

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	23 Oct 2020 19:02:37

US3372394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	23 Oct 2020 19:02:37

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '30 Oct 2020'	(b) (4) Alexandra Arango (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	30 Oct 2020 15:12:06

US3372394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	30 Oct 2020 15:12:06

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:55:28
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: sample dated 02 FEB 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)	22 Feb 2021 08:04:40
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: sample dated 02 FEB 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).	Peter Jacob (b) (4) (b) (4)	20 Feb 2021 17:20:29
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: sample dated 02 FEB 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)	12 Feb 2021 10:00:18
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 02 FEB 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 and then update the details under appropriate visit' canceled (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:59:36
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 02 FEB 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 and then update the details under appropriate visit' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:49:21

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:55:28
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:55:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'VISIT3'	System	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:33

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:33

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered '09:30'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered '6 Nov 2020 09:30'	System	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:11:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:03:56

US3372394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	06 Nov 2020 15:03:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 64'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:27:23', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered 'Yes (Y)'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with 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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:27:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered 'No (N)'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:27:44', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered 'No (N)'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:27:54', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered 'Yes (Y)'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Please 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 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:28:02', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-14T11:28:25', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '5bd36493-8b5a-400e-85bc-4512dc13bbe9'	System	14 Nov 2020 16:28:36
User entered '14 Nov 2020 11:28:25'	System	14 Nov 2020 16:28:36

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:08:39
Data entry locked.	System	11 Sep 2020 15:30:29
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56
Data entry locked.	System	11 Sep 2020 15:30:29
User entered 'Day 71'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with 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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Please 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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Please 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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Please 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)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56
Data entry locked.	System	11 Sep 2020 15:30:29
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 15:30:29

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:30:56
Data entry locked.	System	11 Sep 2020 15:30:29
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 15:30:29

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-29T16:04:01', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '095e2840-0ebe-4638-a9ae-08558dd0ae77'	System	29 Nov 2020 21:04:16
User entered 'No (N)'	System	29 Nov 2020 21:04:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-29T16:04:06', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '095e2840-0ebe-4638-a9ae-08558dd0ae77'	System	29 Nov 2020 21:04:16
User entered 'No (N)'	System	29 Nov 2020 21:04:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-11-29T16:04:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '095e2840-0ebe-4638-a9ae-08558dd0ae77'	System	29 Nov 2020 21:04:16
User entered '29 Nov 2020 16:04:14'	System	29 Nov 2020 21:04:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-06T18:01:35', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '08fba05e-2ff2-4c01-9629-3dc00e3cd49c'	System	06 Dec 2020 23:01:52
User entered 'No (N)'	System	06 Dec 2020 23:01:52

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-06T18:01:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '08fba05e-2ff2-4c01-9629-3dc00e3cd49c'	System	06 Dec 2020 23:01:52
User entered 'No (N)'	System	06 Dec 2020 23:01:52

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-06T18:01:49', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '08fba05e-2ff2-4c01-9629-3dc00e3cd49c'	System	06 Dec 2020 23:01:52
User entered '06 Dec 2020 18:01:49'	System	06 Dec 2020 23:01:52

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-15T16:43:34', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'db371545-c2fe-4196-823b-7fd4fa4b1e92'	System	15 Dec 2020 21:43:58
User entered 'No (N)'	System	15 Dec 2020 21:43:58

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-15T16:43:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'db371545-c2fe-4196-823b-7fd4fa4b1e92'	System	15 Dec 2020 21:43:58
User entered 'No (N)'	System	15 Dec 2020 21:43:58

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-15T16:43:50', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'db371545-c2fe-4196-823b-7fd4fa4b1e92'	System	15 Dec 2020 21:43:58
User entered '15 Dec 2020 16:43:50'	System	15 Dec 2020 21:43:58

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-27T08:11:30', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c3dc14da-2db8-4061-9aa3-f3bf65e64b18'	System	27 Dec 2020 13:11:47
User entered 'No (N)'	System	27 Dec 2020 13:11:47

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-27T08:11:36', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c3dc14da-2db8-4061-9aa3-f3bf65e64b18'	System	27 Dec 2020 13:11:47
User entered 'No (N)'	System	27 Dec 2020 13:11:47

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2020-12-27T08:11:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c3dc14da-2db8-4061-9aa3-f3bf65e64b18'	System	27 Dec 2020 13:11:47
User entered '27 Dec 2020 08:11:43'	System	27 Dec 2020 13:11:47

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2021-01-10T00:03:28', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac167204-919b-4767-b60f-a15fc8cea017'	System	10 Jan 2021 05:04:41
User entered 'No (N)'	System	10 Jan 2021 05:04:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2021-01-10T00:03:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac167204-919b-4767-b60f-a15fc8cea017'	System	10 Jan 2021 05:04:41
User entered 'No (N)'	System	10 Jan 2021 05:04:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eae96eadb999f17d)', Time: '2021-01-10T00:03:40', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac167204-919b-4767-b60f-a15fc8cea017'	System	10 Jan 2021 05:04:41
User entered '10 Jan 2021 00:03:40'	System	10 Jan 2021 05:04:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-21T13:27:56', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'a314b0b1-b721-4968-864a-8263d28b8605'	System	21 Jan 2021 18:28:07
User entered 'No (N)'	System	21 Jan 2021 18:28:07

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-21T13:28:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'a314b0b1-b721-4968-864a-8263d28b8605'	System	21 Jan 2021 18:28:07
User entered 'No (N)'	System	21 Jan 2021 18:28:07

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-21T13:28:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'a314b0b1-b721-4968-864a-8263d28b8605' User entered '21 Jan 2021 13:28:04'	System	21 Jan 2021 18:28:07

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-24T08:15:13', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'de4e3e15-667b-4b88-a919-76a3d780b44f'	System	24 Jan 2021 13:15:35
User entered 'No (N)'	System	24 Jan 2021 13:15:35

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-24T08:15:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'de4e3e15-667b-4b88-a919-76a3d780b44f'	System	24 Jan 2021 13:15:35
User entered 'No (N)'	System	24 Jan 2021 13:15:35

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-24T08:15:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'de4e3e15-667b-4b88-a919-76a3d780b44f' User entered '24 Jan 2021 08:15:32'	System	24 Jan 2021 13:15:35
	System	24 Jan 2021 13:15:35

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:54:27', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered 'Yes (Y)'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:54:32', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered 'No (N)'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:54:37', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered 'Yes (Y)'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '1'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '1'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '1'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '1'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '1'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8' User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '0'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:09', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:14', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered 'No (N)'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-01-31T08:55:39', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'acf6f9f7-c07f-4728-92f7-7efc74a68bd8'	System	31 Jan 2021 13:55:49
User entered '31 Jan 2021 08:55:39'	System	31 Jan 2021 13:55:49

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-08T13:49:15', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7c562d23-c309-4281-815d-7dc216850e72'	System	08 Feb 2021 18:49:43
User entered 'No (N)'	System	08 Feb 2021 18:49:43

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-08T13:49:20', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7c562d23-c309-4281-815d-7dc216850e72'	System	08 Feb 2021 18:49:43
User entered 'No (N)'	System	08 Feb 2021 18:49:43

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-08T13:49:43', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7c562d23-c309-4281-815d-7dc216850e72'	System	08 Feb 2021 18:49:43
User entered '08 Feb 2021 13:49:43'	System	08 Feb 2021 18:49:43

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-14T10:19:04', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '59685180-ec19-40f8-bd0d-fa704d2134d8'	System	14 Feb 2021 15:19:20
User entered 'No (N)'	System	14 Feb 2021 15:19:20

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-14T10:19:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '59685180-ec19-40f8-bd0d-fa704d2134d8'	System	14 Feb 2021 15:19:20
User entered 'No (N)'	System	14 Feb 2021 15:19:20

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-14T10:19:18', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '59685180-ec19-40f8-bd0d-fa704d2134d8' User entered '14 Feb 2021 10:19:18'	System	14 Feb 2021 15:19:20
	System	14 Feb 2021 15:19:20

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-22T18:09:07', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '309bd141-5aed-4306-b1d1-bd2d4caa0519'	System	22 Feb 2021 23:13:11
User entered 'No (N)'	System	22 Feb 2021 23:13:11

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-22T18:09:11', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '309bd141-5aed-4306-b1d1-bd2d4caa0519'	System	22 Feb 2021 23:13:11
User entered 'No (N)'	System	22 Feb 2021 23:13:11

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-02-22T18:09:16', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '309bd141-5aed-4306-b1d1-bd2d4caa0519'	System	22 Feb 2021 23:13:11
User entered '22 Feb 2021 18:09:16'	System	22 Feb 2021 23:13:11

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-01T14:28:33-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '952f850b-f241-48bd-85c3-3808d602da6b'	System	01 Mar 2021 19:28:42
User entered 'No (N)'	System	01 Mar 2021 19:28:42

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-01T14:28:36-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '952f850b-f241-48bd-85c3-3808d602da6b'	System	01 Mar 2021 19:28:42
User entered 'No (N)'	System	01 Mar 2021 19:28:42

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-01T14:28:40-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '952f850b-f241-48bd-85c3-3808d602da6b' User entered '01 Mar 2021 14:28:40'	System	01 Mar 2021 19:28:42
	System	01 Mar 2021 19:28:42

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-08T11:01:58-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba279c78-74e8-4f73-97db-1a28414b25f1'	System	08 Mar 2021 16:02:19
User entered 'No (N)'	System	08 Mar 2021 16:02:19

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-08T11:02:01-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba279c78-74e8-4f73-97db-1a28414b25f1'	System	08 Mar 2021 16:02:19
User entered 'No (N)'	System	08 Mar 2021 16:02:19

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-08T11:02:05-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ba279c78-74e8-4f73-97db-1a28414b25f1' User entered '08 Mar 2021 11:02:05'	System	08 Mar 2021 16:02:19
	System	08 Mar 2021 16:02:19

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-14T00:07:59-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7412c17d-3689-4887-9427-18272cffd70b'	System	14 Mar 2021 05:10:16
User entered 'No (N)'	System	14 Mar 2021 05:10:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-14T00:08:04-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7412c17d-3689-4887-9427-18272cffd70b'	System	14 Mar 2021 05:10:16
User entered 'No (N)'	System	14 Mar 2021 05:10:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-14T00:08:12-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '7412c17d-3689-4887-9427-18272cffd70b' User entered '14 Mar 2021 00:08:12'	System	14 Mar 2021 05:10:16
	System	14 Mar 2021 05:10:16

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-21T19:45:26-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'e09c747e-23d9-4b4d-8db1-9ce8acf67846'	System	21 Mar 2021 23:45:37
User entered 'No (N)'	System	21 Mar 2021 23:45:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-21T19:45:29-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'e09c747e-23d9-4b4d-8db1-9ce8acf67846'	System	21 Mar 2021 23:45:37
User entered 'No (N)'	System	21 Mar 2021 23:45:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-21T19:45:35-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'e09c747e-23d9-4b4d-8db1-9ce8acf67846' User entered '21 Mar 2021 19:45:35'	System	21 Mar 2021 23:45:37
	System	21 Mar 2021 23:45:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-28T07:46:14-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac5d24a4-6e0d-446a-ade6-f9fdf3422a31'	System	28 Mar 2021 11:46:26
User entered 'No (N)'	System	28 Mar 2021 11:46:26

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-28T07:46:20-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac5d24a4-6e0d-446a-ade6-f9fdf3422a31'	System	28 Mar 2021 11:46:26
User entered 'No (N)'	System	28 Mar 2021 11:46:26

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-28T07:46:24-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ac5d24a4-6e0d-446a-ade6-f9fdf3422a31' User entered '28 Mar 2021 07:46:24'	System	28 Mar 2021 11:46:26
	System	28 Mar 2021 11:46:26

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-06T23:57:39-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c7a8b27e-0cd2-4f81-a9c3-d4c56504089e' User entered 'No (N)'	System	07 Apr 2021 03:57:51
	System	07 Apr 2021 03:57:51

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-06T23:57:43-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c7a8b27e-0cd2-4f81-a9c3-d4c56504089e'	System	07 Apr 2021 03:57:51
User entered 'No (N)'	System	07 Apr 2021 03:57:51

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-06T23:57:48-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'c7a8b27e-0cd2-4f81-a9c3-d4c56504089e' User entered '06 Apr 2021 23:57:48'	System	07 Apr 2021 03:57:51
	System	07 Apr 2021 03:57:51

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-18T10:33:32-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '21f362d4-f6c0-4c5d-a1ca-61ab50930132'	System	18 Apr 2021 14:33:41
User entered 'No (N)'	System	18 Apr 2021 14:33:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-18T10:33:35-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '21f362d4-f6c0-4c5d-a1ca-61ab50930132'	System	18 Apr 2021 14:33:41
User entered 'No (N)'	System	18 Apr 2021 14:33:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-18T10:33:39-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '21f362d4-f6c0-4c5d-a1ca-61ab50930132'	System	18 Apr 2021 14:33:41
User entered '18 Apr 2021 10:33:39'	System	18 Apr 2021 14:33:41

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-25T17:27:27-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6dcff679-219f-4560-8433-0def8d6b6bb3'	System	25 Apr 2021 21:27:37
User entered 'No (N)'	System	25 Apr 2021 21:27:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-25T17:27:30-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6dcff679-219f-4560-8433-0def8d6b6bb3'	System	25 Apr 2021 21:27:37
User entered 'No (N)'	System	25 Apr 2021 21:27:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-04-25T17:27:34-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: '6dcff679-219f-4560-8433-0def8d6b6bb3'	System	25 Apr 2021 21:27:37
User entered '25 Apr 2021 17:27:34'	System	25 Apr 2021 21:27:37

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-05-02T00:39:18-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec488850-5e3b-4ad2-9c22-6d3acc8b21d5'	System	02 May 2021 04:39:30
User entered 'No (N)'	System	02 May 2021 04:39:30

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-05-02T00:39:22-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec488850-5e3b-4ad2-9c22-6d3acc8b21d5'	System	02 May 2021 04:39:30
User entered 'No (N)'	System	02 May 2021 04:39:30

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-05-02T00:39:28-04:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'ec488850-5e3b-4ad2-9c22-6d3acc8b21d5'	System	02 May 2021 04:39:30
User entered '02 May 2021 00:39:28'	System	02 May 2021 04:39:30

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:18:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:30:56

US3372394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:18:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-01T14:28:46-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'a8d66144-8014-4b2e-bced-d983bff72c1e'	System	01 Mar 2021 19:28:53
User entered 'No (N)'	System	01 Mar 2021 19:28:53

US3372394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:18:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:30:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa8eef3fc22a8cd1)', Time: '2021-03-01T14:28:50-05:00', User OID: 'PatientReportedOutcome (US3372394)', ODM File OID: 'a8d66144-8014-4b2e-bced-d983bff72c1e' User entered '01 Mar 2021 14:28:50'	System	01 Mar 2021 19:28:53
	System	01 Mar 2021 19:28:53

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	04 Dec 2020 16:46:00

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '04 Dec 2020'	(b) (4) Danielle Theodore (b) (4) (b) (4)	04 Dec 2020 16:46:00

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	04 Dec 2020 16:46:00

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Danielle Theodore (b) (4)	04 Dec 2020 16:46:00
	(b) (4)	

US3372394

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	04 Dec 2020 16:46:07

US3372394

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:33:06
User entered 'I'	System	04 Dec 2020 16:46:07

US3372394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 15:58:17

US3372394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered '7 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 15:58:17

US3372394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 15:58:17

US3372394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:46:04
User entered empty.	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 15:58:17
	(b) (4)	

US3372394

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 15:58:23

US3372394

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User entered 'I'	System	07 Jan 2021 15:58:23

US3372394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-Feb-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:37:21
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 3 Sample with collection date of 04 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in saliva log under Illness visit folder in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:54:46
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-Feb-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	19 Feb 2021 20:36:02
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 3 Sample with collection date of 04 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in saliva log under Illness visit folder in EDC. Thank you.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	19 Feb 2021 20:35:57
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-Feb-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 05:00:43

US3372394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of 06 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in saliva log under Illness visit folder in EDC. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:54:51
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of 06 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in saliva log under Illness visit folder in EDC. Thank you. ' answered with 'data updated' (Site from DM).	(b) (4)	
User entered '06 Feb 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Feb 2021 20:36:07
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of 06 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in saliva log under Illness visit folder in EDC. Thank you. ' (Site from DM).	(b) (4)	
User entered '6 Feb 2021'	Peter Jacob (b) (4)	19 Feb 2021 20:06:29
	(b) (4)	
	(b) (4), (b) (6)	15 Feb 2021 12:53:49
	Danielle Theodore (b) (4)	07 Feb 2021 00:12:29
	(b) (4)	

US3372394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	07 Feb 2021 00:12:29

US3372394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Danielle Theodore (b) (4)	07 Feb 2021 00:12:29
	(b) (4)	

US3372394

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:50:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	07 Feb 2021 00:12:37
	(b) (4)	

US3372394

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User entered 'I'	System	07 Feb 2021 00:12:37

US3372394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Mar 2021 16:20:42
	(b) (4)	

US3372394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	08 Mar 2021 16:20:42
	(b) (4)	

US3372394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	08 Mar 2021 16:20:42

US3372394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:18:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	08 Mar 2021 16:20:42
	(b) (4)	

US3372394

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Mar 2021 16:20:49
	(b) (4)	

US3372394

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:31:27
User entered 'I'	System	08 Mar 2021 16:20:49

US3372394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:10

US3372394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:10

US3372394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:10

US3372394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 16:18:10

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:56:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:18:17

US3372394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:24

US3372394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:24

US3372394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:39

US3372394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:39

US3372394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered '10:25'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:39

US3372394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 10:25'	System	13 Apr 2021 16:18:39

US3372394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:55:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:18:46

US3372394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:18:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:18:46

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:18:43

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:12:54
User entered '02 Feb 2021'	Peter Jacob (b) (4)	19 Feb 2021 20:12:22
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:18:43

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '09:30'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:12:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:18:43

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:16
User entered '01 Feb 2021 09:30'	System	19 Feb 2021 20:12:54
User entered '02 Feb 2021 09:30'	System	19 Feb 2021 20:12:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:18:43

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:12:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:18:43

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:12:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User closed query 'Per sponsor review, please verify data and add entry for Symptom Day 2 (02Feb2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 03:07:26
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 01Feb2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 03:07:23
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
Query 'Per sponsor review, please verify data and add entry for Symptom Day 2 (02Feb2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:16:06
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 01Feb2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' answered with 'Day 1 of symptoms was on 26JAN2021. Data updated.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:15:49
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 20:02:34
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 20:02:34
User opened query 'Per sponsor review, please verify data and add entry for Symptom Day 2 (02Feb2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 19:51:35
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 01Feb2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:12:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 7 (Day 7)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:01:18
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 20:01:18
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '98'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.2' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:23:57
User entered 'Mild (Mild)'	Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:23:57
User entered 'Mild (Mild)'	Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:23:57
User entered 'Mild (Mild)'	Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:23:57
User entered 'Mild (Mild)'	Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 20:23:57
User entered 'Mild (Mild)'	Peter Jacob (b) (4)	19 Feb 2021 20:15:24
	(b) (4)	

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 9 (Day 9)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '03 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '98'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.3' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:23:40

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 10 (Day 10)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '04 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '98'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.9' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:24

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 11 (Day 11)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '05 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '100'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '96.8' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:28

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 12 (Day 12)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '06 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '99'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.2' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:32:59

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 13 (Day 13)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '07 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '98'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.9' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:48

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Day 14 (Day 14)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '08 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '98'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '97.1' F	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'None (None)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:22

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:07:16

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:03

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '100.9' F	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:09:58

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:11:07

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:12:14

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:13:08

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User entered '%'	System	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '100.2' F	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:18:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:22
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:14:02

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "01-FEB-2021" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "02-FEB-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated "01-FEB-2021" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "02-FEB-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify.' answered with 'data updated.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:12:18
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 18:31:25
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:31:15
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "01-FEB-2021" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "02-FEB-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Feb 2021 10:37:09
User entered '01 Feb 2021'	Mira Baron (b) (4)	19 Feb 2021 22:35:27
	Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[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)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:18:43

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:27
User entered '0'	System	19 Feb 2021 20:15:38

US3372394

Folder: Covid-19 Assessment 01 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:18:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:15:46

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:31:45

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:45

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '04 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:31:45
	(b) (4)	

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:33:08

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:08

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '06 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:33:08
	(b) (4)	

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:31

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:31

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '08 Feb 2021'	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:34:31
	(b) (4)	

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:18:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:18:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:34:42

US3372394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[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 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered 'SICKD1'	System	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '09:45'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered '01 Feb 2021 09:45'	System	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '161.3' cm	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:16:31
DataPoint set to visible.	(b) (4) System	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '84.4' kg	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:16:31
DataPoint set to visible.	(b) (4) System	19 Feb 2021 20:16:00

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '36.2' C	(b) (4) Peter Jacob (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Other (Other)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'forehead'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '84'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered 'bpm'	System	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered 'breaths/min'	System	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '148'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered 'mmHg'	System	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '91'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User entered 'mmHg'	System	19 Feb 2021 20:16:31

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32

US3372394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:18:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32

US3372394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:37

US3372394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:18:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:37

US3372394

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:18:43

[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 14:49:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:45

US3372394

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:18:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:32
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 FEB 2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 02 FEB 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 06:55:50
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 FEB 2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 02 FEB 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' answered with 'data updated.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:32:12
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 18:32:00
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:32:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 FEB 2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 02 FEB 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:07:22
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:35:27
User entered '01 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Feb 2021 20:16:45

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:11

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:11

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:11

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:18:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:31:11

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:59:35

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:59:35

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:45:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:45:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:07:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:18:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered empty.	System	14 Jan 2021 19:31:46

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:22

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:22

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:12:58
User entered '15:11'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:22

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:18:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '11 Jan 2021 15:11'	System	14 Jan 2021 19:32:22

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:18:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:52:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:35

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:18:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:52:25
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:35

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:18:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:52:25
User entered '15:08'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:32:35

US3372394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:18:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:51:29
User entered '11 Jan 2021 15:08'	System	14 Jan 2021 19:32:35

US3372394

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:18:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:56:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 15:58:29

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:20:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:25
User entered		
'USA-US056-2020-mRNA-1273-P301000008'	System	17 Nov 2020 15:15:20
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 15:15:20

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:08
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Atherosclerotic cardiovascular disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:50:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:50:58
Data point term sent to Coder	System	16 Nov 2020 16:02:56
User entered 'Symptomatic Atherosclerotic Disease.'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:15
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:19
User entered '11 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:52
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 21:50:31
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:35:30
Revised 17 Mar 2021 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.	(b) (4), (b) (6)	23 Apr 2021 19:12:59
Revised 17 Mar 2021 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data updated ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 18:54:03
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:54:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:54:03

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. Revised 17 Mar 2021 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	19 Mar 2021 14:29:03
DataPoint Verified.	Mira Baron (b) (4) (b) (4)	17 Mar 2021 17:56:14
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:08:46 16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 21:50:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 18:54:03
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:54:03
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:54:03
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'remains ongoing' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:13:35
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'remains ongoing' (Site from Safety).	Mary Sergalis (b) (4)	11 Mar 2021 14:28:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:04:54
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:48
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:49
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
User closed query 'PV Query: Since the subject was hospitalized for the event of symptomatic atherosclerotic disease, the appropriate grade should be grade 4 instead of grade 2/Moderate. Please update the severity as such; if the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:06
Query 'PV Query: Since the subject was hospitalized for the event of symptomatic atherosclerotic disease, the appropriate grade should be grade 4 instead of grade 2/Moderate. Please update the severity as such; if the severity is to remain grade 2, please clarify/explain.' answered with 'Hospitalization was for the diagnostic procedures. Symptoms are transient; they can recur at any time. Therefore: ongoing adverse event with moderate grade.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 18:12:52
User opened query 'PV Query: Since the subject was hospitalized for the event of symptomatic atherosclerotic disease, the appropriate grade should be grade 4 instead of grade 2/Moderate. Please update the severity as such; if the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:19:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:26
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Nov 2020 16:03:23
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Nov 2020 16:02:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:08:59
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:09:00
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Nov 2020 16:03:23
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	16 Nov 2020 16:03:23
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:03:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Nov 2020 16:02:21
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:20:35
User entered '11 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 12:10:45
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:47:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:10
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:09:12
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:45
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:47
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:48
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:21:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:21:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:21:40
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:21:38
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 21:50:31
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Apr 2021 19:10:19
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:10:19
	(b) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	System	23 Apr 2021 19:10:19
	(b) (4), (b) (6)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Apr 2021 19:10:02
User closed query 'Please verify, con meds noted in medical records.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:13:57
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
	(b) (4)	
Query 'Please verify, con meds noted in medical records.' answered with '11-NOV-2020' (Site from CRA).	Mary Sergalis (b) (4)	11 Mar 2021 14:29:58
	(b) (4), (b) (6)	
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	11 Mar 2021 14:29:45
	(b) (4), (b) (6)	
User opened query 'Please verify, con meds noted in medical records.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:14:24
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 16:02:21
	(b) (4), (b) (6)	

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 21:50:31
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 09:50:07
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:13:21
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:10:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 19:10:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
User entered '1' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:29:45
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:02
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	28 Apr 2021 21:50:31
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:35:40
Revised 17 Mar 2021 PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.'	(b) (4), (b) (6)	23 Apr 2021 19:13:32
Revised 17 Mar 2021 PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated' (Site from Safety).		
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 18:54:03
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:54:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:54:03

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Revised 17 Mar 2021 PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:28:33
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:13:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'ongoing at present time' (Site from Safety).	Mary Sergalis (b) (4)	11 Mar 2021 14:29:06
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:04:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:57
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:13:58
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Test not done' (Site from Safety).	Mary Sergalis (b) (4)	27 Apr 2021 20:04:57
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:29:30
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:56:14
User closed query 'PV Query: Did the subject have a medical history of symptomatic atherosclerotic disease? Was the SAE considered a worsening of the subject's medical history of symptomatic atherosclerotic disease?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:14:11
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:14:08
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:13:59
Query 'PV Query: Did the subject have a medical history of symptomatic atherosclerotic disease? Was the SAE considered a worsening of the subject's medical history of symptomatic atherosclerotic disease?' answered with 'No history. Discharge summary sent' (Site from Safety).	Mary Sergalis (b) (4)	11 Mar 2021 14:38:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant lab/diagnostic test sffed' (Site from Safety).	Mary Sergalis (b) (4)	11 Mar 2021 14:31:35

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with '11-NOV-2020' (Site from Safety).	Mary Sergalis (b) (4)	11 Mar 2021 14:30:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 13:23:11
User opened query 'PV Query: Did the subject have a medical history of symptomatic atherosclerotic disease? Was the SAE considered a worsening of the subject's medical history of symptomatic atherosclerotic disease?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:05:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:05:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:05:11
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:05:03
User entered 'Subject US3372394. Phone Call 16 November 2020. 10:10 Hours. Follow-up Safety Alert. Subject US3372394 was hospitalized at Cleveland Clinic Vero Beach Indian River from 11 November 2020 till 13 November 2020 with a diagnosis of Symptomatic Atherosclerotic Disease. She is asymptomatic.'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

2217 of 2548

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:18:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 16:02:21

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:18:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:54:29
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:59:20

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User closed query 'Please verify if the following medications noted in the hospital records should be entered: ASA 81 mg. 11/11/2020, Clopidogrel .75 mg. qd 11/11/20, Sodium Chloride IV 500 ml 11/11-11/11/2020, Regular insulin 2 units sq.11/11/2020.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Mira Baron (b) (4)	23 Mar 2021 16:12:40 16 Mar 2021 19:32:15
Query 'Please verify if the following medications noted in the hospital records should be entered: ASA 81 mg. 11/11/2020, Clopidogrel .75 mg. qd 11/11/20, Sodium Chloride IV 500 ml 11/11-11/11/2020, Regular insulin 2 units sq.11/11/2020.' answered with '11-NOV-2020' (Site from CRA).	Mary Sergalis (b) (4)	11 Mar 2021 14:26:40
User opened query 'Please verify if the following medications noted in the hospital records should be entered: ASA 81 mg. 11/11/2020, Clopidogrel .75 mg. qd 11/11/20, Sodium Chloride IV 500 ml 11/11-11/11/2020, Regular insulin 2 units sq.11/11/2020.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:07:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:01:52
Data point term sent to Coder	System	28 Sep 2020 22:01:07
User entered 'metformin'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'diabetes mellitus type II'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '1000'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'twice daily (BID)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '17 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User entered '2'	System	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User entered '1'	System	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:17
User entered '804 (804)'	System	28 Sep 2020 22:00:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 22:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:01:52
Data point term sent to Coder	System	28 Sep 2020 22:01:05
User entered 'simvastatin'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'hypercholesterolemia'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '10'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un Feb 2019'	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:00:45
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 22:00:45

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 22:02:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:02:52
Data point term sent to Coder	System	28 Sep 2020 22:02:08
User entered 'losartan'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'hypertension'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '50'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un UNK 2010'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:01:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 22:01:11

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:02:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:02:53
Data point term sent to Coder	System	28 Sep 2020 22:02:09
User entered 'vitamin B12'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '2500'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'ug (ug)'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un UNK 2016'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:02:06
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 22:02:06

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Sep 2020 22:04:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:04:55
Data point term sent to Coder	System	28 Sep 2020 22:04:11
User entered 'vitamin D3'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '50'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'ug (ug)'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un UNK 2016'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 22:03:32

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, PRODUCT: CINNAMOMUM VERUM, PRODUCTSYNONYM: CINNAMON [CINNAMOMUM VERUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 06:04:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:04:50
Data point term sent to Coder	System	28 Sep 2020 22:05:12
User entered 'cinnamon supplement'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '500'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'twice daily (BID)'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un UNK 2019'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 22:04:16
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 22:04:16

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
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)	28 Sep 2020 22:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:06:41
Data point term sent to Coder	System	28 Sep 2020 22:05:12
User entered 'influenza vaccine'	Peter Jacob (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User entered empty.	System	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User entered empty.	System	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:06
User entered empty.	System	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 22:06:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:06:42
Data point term sent to Coder	System	28 Sep 2020 22:06:14
User entered 'pneumonia vaccine'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '26 Apr 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '26 Apr 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User entered empty.	System	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User entered empty.	System	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:29
User entered empty.	System	28 Sep 2020 22:05:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:07:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:07:43
Data point term sent to Coder	System	28 Sep 2020 22:07:14
User entered 'shingles vaccine'	Peter Jacob (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '22 May 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '22 May 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User entered empty.	System	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User entered empty.	System	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:48
User entered empty.	System	28 Sep 2020 22:06:29

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:07:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:07:43
Data point term sent to Coder	System	28 Sep 2020 22:07:14
User entered 'shingles vaccine'	Peter Jacob (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Aug 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Aug 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User entered empty.	System	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User entered empty.	System	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:59
User entered empty.	System	28 Sep 2020 22:07:02

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
Query 'Please verify if the following medications noted in the hospital records should be entered: Clopidogrel .75 mg. qd 11/11/20, Sodium Chloride IV 500 ml 11/11-11/11/2020, Regular insulin 2 units sq.11/11/2020.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:01:40
User opened query 'Please verify if the following medications noted in the hospital records should be entered: Clopidogrel .75 mg. qd 11/11/20, Sodium Chloride IV 500 ml 11/11-11/11/2020, Regular insulin 2 units sq.11/11/2020.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:00:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:19:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:19:31
Data point term sent to Coder	System	15 Oct 2020 15:49:49
User entered 'metformin'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'diabetes mellitus type IIq'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '500'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'twice daily (BID)'	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '05 Oct 2020'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 14:18:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	11 Mar 2021 14:18:49
Data point term sent to Coder	System	11 Mar 2021 14:18:32
User entered 'Aspirin'	Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Cardiac Prophylaxis'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '81'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once daily (QD)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '13 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User entered '1'	System	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User entered '1'	System	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:46
User entered '804 (804)'	System	11 Mar 2021 14:17:42

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 14:24:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 14:24:49
Data point term sent to Coder	System	11 Mar 2021 14:23:37
User entered 'Clopidogrel'	Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Cardiac Prophylaxis'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '75'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once daily (QD)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Oral (ORAL)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '12 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	16 Mar 2021 12:59:12
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'un Feb 2021' reason for change: Data Entry Error	Mary Sergalis (b) (4)	16 Mar 2021 12:59:12
User entered empty.	Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User entered '1'	System	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User entered '1'	System	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:41:56
User entered '804 (804)'	System	11 Mar 2021 14:22:58

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:28:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:28:25
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Mar 2021 19:32:15
Data point term sent to Coder	System	11 Mar 2021 14:26:38
User entered 'Regular Insulin'	Mary Sergalis (b) (4) (b) (4) (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Diabetes Mellitus Type II'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '2'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Other (OTHER)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Units'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '0'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User entered empty.	System	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User entered empty.	System	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:18:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:39
User entered empty.	System	11 Mar 2021 14:26:14

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:18:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:18
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:00
User closed query 'Please verify if CT head and MRI brain noted 11/11/2020 in the hospital records should be entered.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:13:08
Query 'Please verify if CT head and MRI brain noted 11/11/2020 in the hospital records should be entered.'	Mary Sergalis (b) (4)	11 Mar 2021 14:02:27
answered with 'updated' (Site from CRA).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	11 Mar 2021 14:02:21
User opened query 'Please verify if CT head and MRI brain noted 11/11/2020 in the hospital records should be entered.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:02:29
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:59:04

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:18:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered '11 Nov 2020'	Mary Sergalis (b) (4)	11 Mar 2021 14:03:18

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:18:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered 'CAT Scan Head'	Mary Sergalis (b) (4)	11 Mar 2021 14:03:18

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:03:18

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:18:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	11 Mar 2021 14:03:18

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:18:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:20
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '11 Nov 2020'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:04:02

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:18:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:20
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'MRI Brain'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:04:02

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:18:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:20
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:04:02

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:18:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:20
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered empty.	(b) (4) Mary Sergalis (b) (4)	11 Mar 2021 14:04:02

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'USA-US056-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:48
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:55
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Mira'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Baron'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '2277 Palm beach Lakes Blvd'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'West Palm Beach'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '33409'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:15:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:04
User entered 'US'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:36:08
User entered '2'	System	12 Mar 2021 19:15:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
	(b) (4)	
User entered '1'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'USA-US056-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:48
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:55
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Mira'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Baron'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '2277 Palm beach Lakes Blvd'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'West Palm Beach'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '33409'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:15:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:04
User entered 'US'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:36:08
User entered '2'	System	12 Mar 2021 19:15:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
	(b) (4)	
User entered '1'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:18:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:23
User entered '17/Nov/2020 15:15'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:18:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:15:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:22
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'USA-US056-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:48
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:55
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Mira'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Baron'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '2277 Palm beach Lakes Blvd'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'West Palm Beach'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '33409'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:15:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:04
User entered 'US'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:36:08
User entered '2'	System	12 Mar 2021 19:15:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
	(b) (4)	
User entered '1'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:18:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered '12/Mar/2021 14:15'	(b) (4) System	12 Mar 2021 19:15:58

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:18:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:32:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:15:58

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'USA-US056-2020-MRNA-1273-P301000008'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:48
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Yes (Y)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'No (N)'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:55
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Mira'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'Baron'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '2277 Palm beach Lakes Blvd'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:14:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered 'West Palm Beach'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:15:44
User entered '33409'	System	17 Nov 2020 15:15:20

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:15:27
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:15:04
User entered 'US'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:18:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:36:08
User entered '2'	System	12 Mar 2021 19:15:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:41
	(b) (4)	
User entered '1'	System	17 Nov 2020 15:15:49

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:18:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered '26/Apr/2021 10:36'	(b) (4) System	26 Apr 2021 14:36:08

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:18:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:42:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:36:08