

US3372394 (Prod: Palm Beach Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:02:26

All time stamps listed in this document are displayed in GMT

US3372394

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:26

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:26

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

Condition	FALLOPIAN TUBE FIMBRIAE FUSION
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

Condition	BILATERAL CUFF TUBOPLASTY
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

Condition	FRACTURED RIGHT WRIST
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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 ☐ No ☒
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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

Condition	TOTAL HIP REPLACEMENT LEFT
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

Condition	OSTEOARTHRITIS OF LEFT HIP
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

Condition	TOTAL HIP REPLACEMENT RIGHT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

Condition	OSTEOARTHRITIS RIGHT HIP
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

Condition	PELVIC INFLAMMATORY DISEASE
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

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.

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 1998
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:50 (24 HR)
Collection date and time (derived)	11 SEP 2020 10:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:26

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:26

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:26

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:26

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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 ☒

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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 ☒

US3372394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

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 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:02:26

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	09 OCT 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:02:26

Collection date (<i>dd MMM yyyy</i>)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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 ☒

US3372394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:26

Yes ☐	
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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Yes ☐	
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

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

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26 NOV 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

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03 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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06 DEC 2020 00:01

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10 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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17 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 103

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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24 DEC 2020 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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07 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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14 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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21 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

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28 JAN 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

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04 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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07 MAR 2021 00:01

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11 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

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18 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

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25 MAR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

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08 APR 2021 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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 contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 376

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

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

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

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

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

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

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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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13 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 516

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

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

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

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

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

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

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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17 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:02:26

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 ☐ 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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 642

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

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

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

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

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

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

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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19 JUN 2022 00:01

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23 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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°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: 26 Nov 2020 11:02:26

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

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26 JUN 2022 00:01

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30 JUN 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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10 JUL 2022 00:01

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US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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21 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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28 JUL 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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04 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:02:26

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:02:26

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:02:26

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 ☐ 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: 26 Nov 2020 11:02:26

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3372394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372394

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:02:26

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3372394

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:02:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372394

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:26

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)

Generated On: 26 Nov 2020 11:02:26

AEID	USA-US056-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC ATHEROSCLEROTIC DISEASE.
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

344 of 1820

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

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

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

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)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		UN FEB 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intraocular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:26

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		27 AUG 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intraocular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:26

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 APR 2018
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 APR 2018
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intraocular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:26

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		22 MAY 2018
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intraocular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:26

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 AUG 2018	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		11 AUG 2018
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:26

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 ☐ Intramuscular ☐

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3372394

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

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

Generated On: 26 Nov 2020 11:02:26

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	1

US3372394

Folder: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:26

SAEID	USA-US056-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	1
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

Audit

US3372394 (Prod: Palm Beach Research Center)

US3372394

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:26

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3372394'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:29:42

US3372394

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
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) (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. ' answered with 'data updated ' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 23:29:10
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 13:29:43

US3372394

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 15:12:08

US3372394

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Sep 2020 15:12:08

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 13:29:44

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Age](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '68'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:26

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 15:12:23

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:12:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 13:29:43

US3372394

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:12:50

US3372394

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:47:20

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2008'	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:16

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2005'	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:26

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2010'	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:48:38

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1976'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1976'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1976'	System	28 Sep 2020 21:48:58

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic 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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1976'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1976'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1976'	System	28 Sep 2020 21:49:18

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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) (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) (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) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1980'	System	28 Sep 2020 21:49:43

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1980'	System	28 Sep 2020 21:50:06

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Sep 2020 21:50:59

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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) (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) (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) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Sep 2020 21:52:12

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2009'	System	28 Sep 2020 21:52:29

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

Condition

Audit	User	Time (GMT)
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) (6)	20 Nov 2020 20:38:09
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)	20 Nov 2020 19:37:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(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).	Coder Import (b) (4)	20 Nov 2020 19:37:02
Data point term sent to Coder	Peter Jacob (b) (4)	20 Nov 2020 19:35:38
Coding entries removed.	(b) (4)	
User entered 'osteoARTHRITIS OF LEFT HIP' reason for change: Data Entry Error	Peter Jacob (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)	20 Nov 2020 19:35:30
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.	(b) (4), (b) (6)	20 Nov 2020 19:35:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	27 Oct 2020 10:52:30
Data point term sent to Coder		
User entered 'arthritis of left hip'	Coder Import (b) (4)	29 Sep 2020 06:15:51
	(b) (4)	
	Coder Import (b) (4)	29 Sep 2020 06:15:51
	(b) (4)	
	System	28 Sep 2020 21:52:55
	Peter Jacob (b) (4)	28 Sep 2020 21:52:45
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	28 Sep 2020 21:52:45

US3372394

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2009'	System	28 Sep 2020 21:52:45

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2012'	System	28 Sep 2020 21:53:11

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	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)	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)	20 Nov 2020 19:36:08
Coding entries removed.	Peter Jacob (b) (4)	20 Nov 2020 19:35:58
User entered 'osteoARTHRITIS RIGHT HIP' reason for change: Data Entry Error	Peter Jacob (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
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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Sep 2020 21:54:42
User: Coder System - version MedDRA\\23.0.	(b) (4)	
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)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '2012'	System	28 Sep 2020 21:53:39

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1979'	System	28 Sep 2020 21:54:01

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: 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
	(b) (4)	

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1998'	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:54:18

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:21'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:21'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '161.3' cm	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '85.6' kg	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: 26 Nov 2020 11:02:26

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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)	25 Sep 2020 18:12:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(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)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered '71'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered '16'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered '127'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 18:11:59
User entered '84'	Peter Jacob (b) (4)	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:36:24

US3372394

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:41

US3372394

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:36:41

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:02:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:04

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

[Specify](#)

Audit	User	Time (GMT)
User entered 'retired'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '1'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:26

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:37:38

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Sep 2020 15:13:13

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '190576'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:55:07

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:16:04

US3372394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4)	28 Sep 2020 21:59:14
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 11:02:26

Height

Audit	User	Time (GMT)
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) (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)	25 Sep 2020 16:55:46
answered with 'done' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 16:54:36
	(b) (4)	
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)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Height

Audit	User	Time (GMT)
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) (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)	25 Sep 2020 16:55:46
answered with 'done' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (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)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:21'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	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: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	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: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	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: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	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: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Height

Audit	User	Time (GMT)
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) (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)	25 Sep 2020 16:55:46
answered with 'done' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (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)	18 Sep 2020 18:38:35
	(b) (4)	

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 16:54:36
User entered '85.6' kg	Peter Jacob (b) (4)	18 Sep 2020 18:38:35

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11:55'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	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: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	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: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	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: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	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: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 18:39:49

US3372394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:55

US3372394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:39:55

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11:20'	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:20'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:30:29

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:50'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:06

US3372394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	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: 26 Nov 2020 11:02:26

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:46'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:40:17

US3372394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Sep 2020 18:40:28

US3372394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:40:28

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	11 Sep 2020 16:04:39
User entered '97.9'	System	11 Sep 2020 16:04:39

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	16 Sep 2020 21:16:51
User entered '97.4'	System	16 Sep 2020 21:16:51

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Sep 2020 20:33:16
User entered '97.0'	System	17 Sep 2020 20:33:16

US3372394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:22

US3372394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:43:26

US3372394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 13:43:26

US3372394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:45:06

US3372394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 13:45:06

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:46

US3372394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	02 Oct 2020 13:49:49

US3372394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 13:49:49

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	15 Oct 2020 15:46:51
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Oct 2020 14:25:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '09:49'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	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: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

Pulse (xxx)

Audit	User	Time (GMT)
User entered '63'	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: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '131'	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: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '81'	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: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 15:47:14

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11:16'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	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: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	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: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '126'	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: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '81'	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: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 15:47:37

US3372394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:44

US3372394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:44

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
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).' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:45:53
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:48
User entered '09 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (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).' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:40:55
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:41'	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 14:43:21

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:15'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:47:57

US3372394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	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: 26 Nov 2020 11:02:26

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '10:13'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:48:05

US3372394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 15:48:08

US3372394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:48:08

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Oct 2020 21:27:39
User entered '99.9'	System	10 Oct 2020 21:27:39

US3372394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-ef05dcaf20b8'	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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-ef05dcaf20b8'	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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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-4675-84d5-324636edd6ac'	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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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-4675-84d5-324636edd6ac'	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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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-4675-84d5-324636edd6ac'	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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-4675-84d5-324636edd6ac'	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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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-4675-84d5-324636edd6ac'	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	16 Oct 2020 19:23:23
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Danielle Theodore (b) (4)	16 Oct 2020 19:23:23
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4) (b) (4) (b) (4)	16 Oct 2020 19:23:23

US3372394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4) (b) (4) (b) (4)	16 Oct 2020 19:23:23

US3372394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4) (b) (4) (b) (4)	16 Oct 2020 19:23:29

US3372394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 19:23:29

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	23 Oct 2020 19:02:27
	(b) (4)	
	(b) (4)	

US3372394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4) (b) (4)	23 Oct 2020 19:02:37

US3372394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:02:37

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:02

US3372394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	30 Oct 2020 15:12:06

US3372394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 15:12:06

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Nov 2020 14:19:00

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:03:27

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:03:33

US3372394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:03:33

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '09:30'	(b) (4), (b) (6)	06 Nov 2020 15:03:52

US3372394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:03:56

US3372394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 15:03:56

US3372394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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: '2020-11-14T11:27:23', 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: 26 Nov 2020 11:02:26

Have you been exposed to someone with 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: '2020-11-14T11:27:39', 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: 26 Nov 2020 11:02:26

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 (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: 26 Nov 2020 11:02:26

[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 (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: 26 Nov 2020 11:02:26

[Please 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 (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: 26 Nov 2020 11:02:26

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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 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: 26 Nov 2020 11:02:26

[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 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: 26 Nov 2020 11:02:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:30:56
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:30:56

US3372394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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 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: 26 Nov 2020 11:02:26

[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 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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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).		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).		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: 26 Nov 2020 11:02:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[None](#)

Audit	User	Time (GMT)
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

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Outcome](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Narrative](#)

Audit	User	Time (GMT)
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

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 16:02:21

US3372394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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)	28 Sep 2020 22:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(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)	28 Sep 2020 22:00:11
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'diabetes mellitus type II'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:02:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:02:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un Feb 2019'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:02:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2500'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 11:02:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	28 Sep 2020 22:03:32
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary 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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	28 Sep 2020 22:05:07

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis/prevention'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'pneumonia prophylaxis/prevention'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '26 Apr 2018'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Apr 2018'	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'herpes zoster prophylaxis/prevention'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '22 May 2018'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 May 2018'	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'herpes zoster prophylaxis/prevention'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:02:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '11 Aug 2018'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2018'	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	15 Oct 2020 15:48:50
	(b) (4)	

US3372394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'diabetes mellitus type IIq'	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: 26 Nov 2020 11:02:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	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: 26 Nov 2020 11:02:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:02:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:02:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:02:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

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

Audit	User	Time (GMT)
User entered '05 Oct 2020'	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: 26 Nov 2020 11:02:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:02:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:02:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:02:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[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: 26 Nov 2020 11:02:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 15:48:50

US3372394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: SAE USA-US056-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:02:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:02:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:15:22
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 15:15:49