

US3522112 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:02:48

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US3522112

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

[Participant ID](#)

US3522112

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

US3522112

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 21:23:39

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Condition	OSTEOARTHRITIS OF BACK, HIPS, WRIST, AND SHOULDERS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522112

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Condition	CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	5 JUL 2017
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JUL 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:25 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:25
Height (<i>xxx.x</i>)	60 in
Weight (<i>xxx.x</i>)	230 lb
BMI (<i>xxx.x</i>)	45.01272 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 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

Data signed: (b) (4) 21 Feb 2021 21:23:39

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Date of assessment (*dd MMM yyyy*) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 21:23:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 185950

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:25
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:02
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

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

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 11:34

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

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	11:17 (24 HR)
Collection date and time (derived)	13 AUG 2020 11:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:19	13 AUG 2020 11:19
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

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: 10 Jun 2021 08:02:48

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 97.5 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 13 AUG 2020 11:56

PC Open Date & Time 13 AUG 2020 11:54

PC Close Date & Time 13 AUG 2020 14:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 13 AUG 2020 19:57

PC Open Date & Time 13 AUG 2020 15:19

PC Close Date & Time 14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

97.9 °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

15 AUG 2020 19:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 22:22

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 20:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

96.5 °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

19 AUG 2020 22:33

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 11:56

PC Open Date & Time

13 AUG 2020 11:54

PC Close Date & Time

13 AUG 2020 14:24

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

13 AUG 2020 19:58

PC Open Date & Time

13 AUG 2020 15:19

PC Close Date & Time

14 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

14 AUG 2020 19:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

15 AUG 2020 19:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

16 AUG 2020 19:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

17 AUG 2020 22:22

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

18 AUG 2020 20:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

19 AUG 2020 22:33

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 11:57
PC Open Date & Time	13 AUG 2020 11:54
PC Close Date & Time	13 AUG 2020 14:24

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 19:59
PC Open Date & Time	13 AUG 2020 15:19
PC Close Date & Time	14 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2114

EAB) (1725)

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 19:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2114

EAB) (1725)

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:16
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

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 ☒

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:43
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 22:23
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 20:44
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:34
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:34

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 AUG 2020 19:34

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 19:35
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3522112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

HAD PAIN DAY 1-4 AT
INJECTION SITE BUT DIDN'T
INTERFERE WITH ACTIVITY
AND RESOLVED. MAY HAVE
HAD SEVERAL DAYS OF MILD
HEADACHE WHICH DID NOT
REQUIRE MEDICATION;
OTHERWISE NO OTHER
CHANGES REPORTED

US3522112

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, OR COVID-19
EXPOSURE RISK

US3522112

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522112

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:34
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:24
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3522112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 10:54 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 10:54

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

US3522112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

10 SEP 2020 10:40

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:43	10 SEP 2020 10:43
Nasopharyngeal Swab 2	No		

US3522112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 11:24

PC Open Date & Time

10 SEP 2020 11:14

PC Close Date & Time

10 SEP 2020 13:44

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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 96.9 °F

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

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

PC Time Stamp	10 SEP 2020 17:22
PC Open Date & Time	10 SEP 2020 14:39
PC Close Date & Time	11 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 17:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

13 SEP 2020 16:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

14 SEP 2020 18:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

15 SEP 2020 17:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:25

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

10 SEP 2020 11:14

PC Open Date & Time

10 SEP 2020 11:14

PC Close Date & Time

10 SEP 2020 13:44

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

10 SEP 2020 17:19

PC Open Date & Time

10 SEP 2020 14:39

PC Close Date & Time

11 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

4

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

12 SEP 2020 17:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

13 SEP 2020 17:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

14 SEP 2020 18:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

15 SEP 2020 17:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

16 SEP 2020 18:25

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 11:15
PC Open Date & Time	10 SEP 2020 11:14
PC Close Date & Time	10 SEP 2020 13:44

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:21
PC Open Date & Time	10 SEP 2020 14:39
PC Close Date & Time	11 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

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 ☒

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

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 ☒

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EAB) (1725)

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

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 ☒

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

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 ☒

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:24
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

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 ☒

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EAB) (1725)

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

		Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 17:13	
PC Open Date & Time	15 SEP 2020 12:00	
PC Close Date & Time	16 SEP 2020 11:59	

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:26
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

DAY 1-2 POST VISIT 2 SLIGHT
ARM SORENESS AND BUMP.
NOTHING SINCE THEN. NO MED
CHANGES, VACCINES, COVID
EXPOSURE, MEDICATION
CHANGE, PREGNANCY RISK.

US3522112

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

If Contact Not Made, please provide Comments

US3522112

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522112

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:41

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:08
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	114 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3522112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

13:19 (24 HR)

Collection date and time (derived)

7 OCT 2020 13:19

US3522112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:44

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 10:02:08
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 08:45:28

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 11:16:12

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 12:11:38
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 11:21:42

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 09:44:58

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 08:32:31
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 10:12:32

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 09:14:09

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 09:49:40

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 09:14:58

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 13:31:16

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 11:05:55

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Date and time of submission

23 JAN 2021 11:26:46

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 12:25:25

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 09:20:36

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 09:35:59

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 09:13:03

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Date and time of submission

27 FEB 2021 15:49:46

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 08:32:06

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 07:10:21

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 10:02:17

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 09:21:30

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 09:02:03

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 08:21:22

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 APR 2021 08:30:54
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 APR 2021 09:39:24
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 10:27:31

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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°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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Patient Cloud Open Date & Time	07 AUG 2021 00:01
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Patient Cloud Close Date & Time	11 AUG 2021 23:59
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US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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°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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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°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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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°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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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28 SEP 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3522112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:02:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:50:05

US3522112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

US3522112

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

US3522112

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

If Contact Not Made, please provide Comments

US3522112

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 FEB 2021

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522112

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 15:15:59

Generated On: 10 Jun 2021 08:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:55:37

Generated On: 10 Jun 2021 08:02:48

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3522112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 15:15:59

Generated On: 10 Jun 2021 08:02:48

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.

US3522112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 15:15:59

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 MAR 2021

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

10 MAR 2021 10:15

US3522112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:15:59

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 11:53:36

Generated On: 10 Jun 2021 08:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

US3522112

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 11:53:36

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522112

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522112

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Mar 2021 18:03:05

Generated On: 10 Jun 2021 08:02:48

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3522112

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3522112

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:03:05

Generated On: 10 Jun 2021 08:02:48

Date of updated informed consent (*dd MMM yyyy*) 13 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 13 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3522112

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

10:28 (24 HR)

Collection date and time (derived)

13 JAN 2021 10:28

US3522112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	10:30
Collection Date and Time (derived)	13 JAN 2021 10:30

US3522112

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 19:00:14

Generated On: 10 Jun 2021 08:02:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

AEID	USA-US131-2021-MRNA-1273-P30 1000016
Adverse event	EXERTIONAL DYSPNEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

PATIENT ADMITTED FOR SOB.
FOUND NEW DIAGNOSIS OF
CHF. LABS ON 13-APR-2021
SHOWED AN ELEVATED
D-DIMER OF 486NG/ML (REF
<255NG/ML) AND BNP 604
PG/ML (REF <100PG/ML) COVID
TESTING WAS
NEGATIVE. 13-APR-2021 CHEST
XRAY RESULTS: IMPRESSION:
THERE IS MILD
CARDIOMEGALY WITHOUT
EVIDENCE OF ACUTE
PULMONARY PROCESS.
PATIENT WAS GIVEN 324 MG
OF ASPIRIN AND 250 MG BOLUS
OF NORMAL SALINE IN THE ED.
ONCE ADMITTED ON THE
FLOOR PATIENT WAS GIVEN IV
LASIX 20 MG
ECHOCARDIOGRAM
14-APR-2021 SHOWED LVEF
15-20% AND PARTICIPANT WAS
REFERRED FOR CARDIAC
CATHETERIZATION.
PARTICIPANT MEDS CHANGED
BUT DOES NOT KNOW THEM
AT THIS TIME. WAITING FOR
DC INFO. RETURNED TO NEW
BASELINE AS OF 4/19/21

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

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

AEID	USA-US131-2021-MRNA-1273-P30 1000016
Adverse event	NEW DIAGNOSIS OF CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

PARTICIPANT RECEIVED NEW
DIAGNOSIS AS A RESULT OF ED
VISIT FOR EXERTIONAL
DYSPNEA. 15-APR-2021 SHE
WAS STARTED ON VALSARTAN
40MG, ONCE DAILY AND WAS
TOLERATING WELL AS OF
19-APR-2021. ON 20-APR-2021
SHE HAD A CORONARY
ANGIOGRAM AND LEFT
VENTRICULAR
GRAM/PRESSURE WHICH
SHOWED NORMAL CORONARY
ARTERIES WITH AN EF OF
25-30% WITH A MARKEDLY
DILATED LEFT VENTRICLE
CONSISTENT WITH A
NONISCHEMIC
CARDIOMYOPATHY. LVEDP
WAS 17 MM HG. CURRENT
PLAN IS TO REPEAT AN
ECHOCARDIOGRAM IN 3
MONTHS TO ASSESS NEED FOR
AN AICD.

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)	
--	--

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

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

Yes ☒

No ☐

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

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	SYNTHROID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	88
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	JANUMET
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NIDDM II
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	DICLOFENAC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	SYMBICORT
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	160/4.5
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
<hr/>		
Start date (dd MMM yyyy) <hr/>		
<hr/>		
Start date completely unknown		True
<hr/>		
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
<hr/>		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		1
<hr/>		
Interval Dosage Unit Number (derived)		1
<hr/>		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input checked="" type="radio"/>
<hr/>		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	S/P PULMONARY EMBOLI
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	EIPEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	0.3
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	CRESTOR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTREMIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	SERTRALINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	FLUTICASONE AND VILANTEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	100-25
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EXERTIONAL DYSPNEA
Dose per administration	324
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	NORMAL SALINE (NACL 0.9%)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EXERTIONAL DYSPNEA
Dose per administration	250
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input checked="" type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	13 APR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____	
Interval Dosage Unit Number (derived) _____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

Name of Medication FUROSEMIDE (LASIX)

Prophylaxis Yes ☐
No ☒

Indication EXERTIONAL DYSPNEA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	PREDNISONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EXERTIONAL DYSPNEA
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

Name of Medication	VALSARTAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NEW DIAGNOSIS OF HEART FAILURE
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:23:39

Generated On: 10 Jun 2021 08:02:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 JAN 2021	STEROID INJECTION BILATERAL SHOULDERS	Medical History	
13 APR 2021	BLOOD DRAW FOR D-DIMER, BNP	Adverse Event	
13 APR 2021	CHEST X-RAY	Adverse Event	
13 APR 2021	COVID-19 TESTING	Adverse Event	
14 APR 2021	ECHOCARDIOGRAM WITHOUT CONTRAST	Adverse Event	
20 APR 2021	CORONARY ANGIOGRAM AND LEFT VENTRICULAR GRAM/PRESSURE	Adverse Event	

US3522112

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:02:48

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

US3522112

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:02:48

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 ☐

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

SAEID	USA-US131-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:48

SAEID	USA-US131-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/APR/2021 15:13
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

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:48

SAEID	USA-US131-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/MAY/2021 11:38
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

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:48

SAEID	USA-US131-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/MAY/2021 13:55
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

US3522112 (Prod: Henry Ford Health System)

US3522112

Form: Participant Creation

Generated On: 10 Jun 2021 08:02:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'US3522112'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:40

US3522112

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:05:29

US3522112

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:41

US3522112

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Clinic (Clinic)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:05:29

US3522112

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'SCRN'	System	13 Aug 2020 14:05:29

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:42

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '71'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'YEARS'	System	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '71'	System	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Female (F)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:06:27

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Aug 2020'	Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'Aug 2020'	System	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '2020'	System	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Amendment 1 (1)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:06

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:41

US3522112

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'I'	System	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:02:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:08:01

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
Data point term sent to Coder	System	13 Aug 2020 14:08:55
User entered 'Asthma'	Yaman Ahmed (b) (4)	13 Aug 2020 14:08:37
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:08:37

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
Data point term sent to Coder	System	13 Aug 2020 14:09:56
User entered 'Spinal Stenosis'	Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:03

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:10:22
Data point term sent to Coder	System	13 Aug 2020 14:09:56
User entered 'Hypothyroidism'	Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:09:27

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
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)	14 Aug 2020 08:16:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:16:04
Data point term sent to Coder	System	13 Aug 2020 14:10:57
User entered 'Hypercholestermia'	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:00
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:00

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:52:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:52:54
Data point term sent to Coder	System	21 Oct 2020 16:29:33
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 16:28:40
User entered 'OSTEOARTHRITIS of back, hips, wrist, and shoulders' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 16:28:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:12:21
Data point term sent to Coder	System	13 Aug 2020 14:11:00
User entered 'Osteoarthritis'	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:24

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 07:47:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:29:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:13:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Venous therapeutic procedures, PT: Vena cava filter insertion, LLT: Vena cava filter insertion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:36:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:36:59
Data point term sent to Coder	System	13 Aug 2020 14:10:58
User entered 'IVC Filter'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	Yaman Ahmed (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 07:46:53
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' answered with 'changed' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:29:45
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:29:32
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:13:15
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '1' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	03 Oct 2020 15:29:32
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:10:44

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:35:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:35:28
Data point term sent to Coder	System	13 Aug 2020 14:12:02
User entered 'S/P Pulmonary Emboli'	Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:09

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:13:26
Data point term sent to Coder	System	13 Aug 2020 14:12:02
User entered 'Cataracts'	Yaman Ahmed (b) (4)	13 Aug 2020 14:11:42
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	13 Jan 2021 15:40:03
User entered 'Yes (Y)'	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:11:42
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '5 Jul 2017' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	13 Jan 2021 15:40:03
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:11:42
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'Jul 2017'	System	13 Jan 2021 15:40:03
User entered empty.	System	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '2017'	System	13 Jan 2021 15:40:03
User entered empty.	System	13 Aug 2020 14:11:42

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
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: NIDDM - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:10:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:10:22
Data point term sent to Coder	System	13 Aug 2020 14:33:58
User entered 'NIDDM II'	Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07
	(b) (4)	

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Aug 2020 14:33:07

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:15:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:15:55
Data point term sent to Coder	System	08 Sep 2020 12:15:02
User entered 'Post Menopause'	Sharon Mathys (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Sharon Mathys (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	08 Sep 2020 12:14:51

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Aug 2020'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '10:25'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '13 Aug 2020 10:25'	System	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '60' in	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16
DataPoint set to visible.	(b) (4) System	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '230' lb	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16
DataPoint set to visible.	(b) (4) System	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
Amendment Manager: User entered '45.01272'	System	16 Sep 2020 23:54:57
User entered '45.0'	System	13 Aug 2020 14:36:16
DataPoint set to visible.	System	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'kg/m2'	System	13 Aug 2020 14:36:16
DataPoint set to visible.	System	13 Aug 2020 14:07:21

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered '96.3' F	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:54:49
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 12:25:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 12:24:56
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:01:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	17 Aug 2020 19:28:32
User entered 'Other (Other)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered 'Infrared'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered '105'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'bpm'	System	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered '20'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'breaths/min'	System	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered '146'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'mmHg'	System	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:32
User entered '95'	Yaman Ahmed (b) (4)	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'mmHg'	System	13 Aug 2020 14:36:16

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46

US3522112

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46

US3522112

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:37:46

US3522112

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 17:47:42
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 14:38:52
User entered '13 Aug 2020'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:46

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 08:00:11
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'added' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:15:25
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:46:01
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	13 Aug 2020 14:38:12
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:38:12
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	13 Aug 2020 14:38:04
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 19:08:02
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	13 Aug 2020 14:38:12
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04
	(b) (4)	

US3522112

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:48

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '1' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:08:02
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:04

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:38:47

US3522112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:39:02

US3522112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:39:02

US3522112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Clinic (Clinic)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:39:02

US3522112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'VISIT1'	System	13 Aug 2020 14:39:02

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:46

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:06:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:06:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 14:04:46
User entered '185950' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:46

US3522112

Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 14:04:46

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:59:01

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:59:01

US3522112

Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:59:01

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:59:01

US3522112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:59:01

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '60' in	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '230' lb	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '60' in	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '230' lb	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Pre-Dose (PREDOSE)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10:25'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '13 Aug 2020 10:25'	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:52:28
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 13:23:34
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:54:57
User entered '96.3' F	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Other (Other)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Sep 2020 13:23:26
User entered 'Infrared'	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:27:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Aug 2020 19:27:55
User entered '105' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 19:27:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 14:37:29
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'bpm'	System	17 Aug 2020 19:27:55
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:27:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Aug 2020 19:27:55
User entered '20' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 19:27:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 14:37:29
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'breaths/min'	System	17 Aug 2020 19:27:55
User entered empty.	System	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:27:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Aug 2020 19:27:55
User entered '146' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 19:27:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 14:37:29
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	17 Aug 2020 19:27:55
User entered empty.	System	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:27:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Aug 2020 19:27:55
User entered '95' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 19:27:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 14:37:29
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	17 Aug 2020 19:27:55
User entered empty.	System	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '60' in	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 19:28:07
User entered '230' lb	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Post-Dose (POSTDOSE)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 15:52:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 15:52:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 15:52:45
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 14:37:29
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	17 Aug 2020 15:34:39
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 16:02:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 16:02:41
User entered '12:02' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '13 Aug 2020 12:02'	System	13 Aug 2020 16:02:41
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '97.5' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Sep 2020 13:23:47
User entered 'Infrared' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 16:02:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 16:02:41
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'bpm'	System	13 Aug 2020 16:02:41
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	13 Aug 2020 16:02:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 16:02:41
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'breaths/min'	System	13 Aug 2020 16:02:41
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 16:02:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 16:02:41
User entered '134' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	13 Aug 2020 16:02:41
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 16:02:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 16:02:41
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 16:02:41
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 15:52:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:37:29
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	13 Aug 2020 16:02:41
User entered empty.	System	13 Aug 2020 14:37:29

US3522112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Aug 2020 16:13:14
User entered 'Yes (Y)'	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:39:12
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 16:13:14
User entered '13 Aug 2020'	Yaman Ahmed (b) (4)	13 Aug 2020 14:39:12

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '11:34'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '13 Aug 2020 11:34'	System	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'ONCE'	System	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 15:37:03

US3522112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 15:25:06

US3522112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020'	Yaman Ahmed (b) (4)	13 Aug 2020 15:25:06

US3522112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '11:17'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 15:25:06

US3522112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '13 Aug 2020 11:17'	System	13 Aug 2020 15:25:06

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '13 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '11:19'	Yaman Ahmed (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '13 Aug 2020 11:19'	System	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 15:28:00
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	13 Aug 2020 15:28:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 15:25:34
	Yaman Ahmed (b) (4)	13 Aug 2020 15:25:34
	(b) (4)	

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered empty.	System	13 Aug 2020 15:25:34

US3522112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:59:19

US3522112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '1'	System	13 Aug 2020 14:59:19

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:55:27', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5'	System	13 Aug 2020 15:56:13
User entered 'Yes (Y)'	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:55:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5' User entered '97.5'	System	13 Aug 2020 15:56:13
	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:55:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5'	System	13 Aug 2020 15:56:13
User entered 'Yes (Y)'	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:55:57', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5' User entered '0'	System	13 Aug 2020 15:56:13
	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted, see source, she took her usual medication, diclofenac for osetoarthritis, which she does every day (con med line 3), rather than a different med for a solicited AR ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:20:30
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 16:30:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:55:57', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5'	System	13 Aug 2020 15:56:13
User entered '1'	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '289029dc-5ddc-4282-a6da-cdf69fe178f5'	System	13 Aug 2020 15:56:13
User entered '13 Aug 2020 11:56'	System	13 Aug 2020 15:56:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 11:54'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 14:24'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b' User entered 'Yes (Y)'	System	13 Aug 2020 23:57:40
	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b' User entered '97.5'	System	13 Aug 2020 23:57:40
	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b'	System	13 Aug 2020 23:57:40
User entered 'Yes (Y)'	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b' User entered '0'	System	13 Aug 2020 23:57:40
	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted, see source, she took her usual medication, diclofenac for osetoarthritis, which she does every day (con med line 3), rather than a different med for a solicited AR ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:20:36
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 16:31:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b'	System	13 Aug 2020 23:57:40
User entered '1'	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d1b96e1-f410-4b09-904b-71e229351b9b' User entered '13 Aug 2020 19:57'	System	13 Aug 2020 23:57:40
	System	13 Aug 2020 23:57:40

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 2'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:23:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '10a008db-983c-496e-9bdf-6b5052e65887' User entered 'Yes (Y)'	System	14 Aug 2020 23:24:13
	System	14 Aug 2020 23:24:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:23:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '10a008db-983c-496e-9bdf-6b5052e65887' User entered '98.2'	System	14 Aug 2020 23:24:13
	System	14 Aug 2020 23:24:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:23:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '10a008db-983c-496e-9bdf-6b5052e65887'	System	14 Aug 2020 23:24:13
User entered 'No (N)'	System	14 Aug 2020 23:24:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:02', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '10a008db-983c-496e-9bdf-6b5052e65887' User entered '14 Aug 2020 19:24'	System	14 Aug 2020 23:24:13
	System	14 Aug 2020 23:24:13

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 3'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:14:20', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6a4fdc57-8a43-4dcb-badf-790935b5ec56'	System	15 Aug 2020 23:15:19
User entered 'Yes (Y)'	System	15 Aug 2020 23:15:19

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6a4fdc57-8a43-4dcb-badf-790935b5ec56' User entered '97.9'	System	15 Aug 2020 23:15:19
	System	15 Aug 2020 23:15:19

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6a4fdc57-8a43-4dcb-badf-790935b5ec56'	System	15 Aug 2020 23:15:19
User entered 'No (N)'	System	15 Aug 2020 23:15:19

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6a4fdc57-8a43-4dcb-badf-790935b5ec56'	System	15 Aug 2020 23:15:19
User entered '15 Aug 2020 19:15'	System	15 Aug 2020 23:15:19

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 4'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:42:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '953b1bea-655e-4ac5-98c8-200c662adc47' User entered 'Yes (Y)'	System	16 Aug 2020 23:43:07
	System	16 Aug 2020 23:43:07

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:42:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '953b1bea-655e-4ac5-98c8-200c662adc47' User entered '98.1'	System	16 Aug 2020 23:43:07
	System	16 Aug 2020 23:43:07

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:42:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '953b1bea-655e-4ac5-98c8-200c662adc47'	System	16 Aug 2020 23:43:07
User entered 'No (N)'	System	16 Aug 2020 23:43:07

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '953b1bea-655e-4ac5-98c8-200c662adc47' User entered '16 Aug 2020 19:43'	System	16 Aug 2020 23:43:07
	System	16 Aug 2020 23:43:07

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 5'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:20', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '25925fba-4978-4cba-bd96-37c1bfbe9216' User entered 'Yes (Y)'	System	18 Aug 2020 02:22:41
	System	18 Aug 2020 02:22:41

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '25925fba-4978-4cba-bd96-37c1bfbe9216' User entered '97.1'	System	18 Aug 2020 02:22:41
	System	18 Aug 2020 02:22:41

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:30', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '25925fba-4978-4cba-bd96-37c1bfbe9216' User entered 'No (N)'	System	18 Aug 2020 02:22:41
	System	18 Aug 2020 02:22:41

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '25925fba-4978-4cba-bd96-37c1bfbe9216' User entered '17 Aug 2020 22:22'	System	18 Aug 2020 02:22:41
	System	18 Aug 2020 02:22:41

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 6'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:43:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '4301237d-51c8-4476-ad9d-142b507f163c' User entered 'Yes (Y)'	System	19 Aug 2020 00:44:06
	System	19 Aug 2020 00:44:06

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:43:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '4301237d-51c8-4476-ad9d-142b507f163c' User entered '97.5'	System	19 Aug 2020 00:44:06
	System	19 Aug 2020 00:44:06

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '4301237d-51c8-4476-ad9d-142b507f163c'	System	19 Aug 2020 00:44:06
User entered 'No (N)'	System	19 Aug 2020 00:44:06

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '4301237d-51c8-4476-ad9d-142b507f163c' User entered '18 Aug 2020 20:44'	System	19 Aug 2020 00:44:06
	System	19 Aug 2020 00:44:06

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 7'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:30:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7707015c-9e38-44ee-95ff-c0d6ce6323d9' User entered 'Yes (Y)'	System	20 Aug 2020 02:33:33
	System	20 Aug 2020 02:33:33

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:20', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7707015c-9e38-44ee-95ff-c0d6ce6323d9' User entered '96.5'	System	20 Aug 2020 02:33:33
	System	20 Aug 2020 02:33:33

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7707015c-9e38-44ee-95ff-c0d6ce6323d9'	System	20 Aug 2020 02:33:33
User entered 'No (N)'	System	20 Aug 2020 02:33:33

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7707015c-9e38-44ee-95ff-c0d6ce6323d9' User entered '19 Aug 2020 22:33'	System	20 Aug 2020 02:33:33
	System	20 Aug 2020 02:33:33

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '472efd91-03f8-416d-8e41-624801e2ecc6'	System	13 Aug 2020 15:56:44
User entered 'None (1)'	System	13 Aug 2020 15:56:44

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '472efd91-03f8-416d-8e41-624801e2ecc6' User entered 'No (N)'	System	13 Aug 2020 15:56:44
	System	13 Aug 2020 15:56:44

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '472efd91-03f8-416d-8e41-624801e2ecc6'	System	13 Aug 2020 15:56:44
User entered 'No (N)'	System	13 Aug 2020 15:56:44

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '472efd91-03f8-416d-8e41-624801e2ecc6'	System	13 Aug 2020 15:56:44
User entered 'None (1)'	System	13 Aug 2020 15:56:44

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '472efd91-03f8-416d-8e41-624801e2ecc6'	System	13 Aug 2020 15:56:44
User entered '13 Aug 2020 11:56'	System	13 Aug 2020 15:56:44

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 11:54'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 14:24'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:57:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f2f3feb6-27d4-41f6-979f-29d9e213e62d'	System	13 Aug 2020 23:58:45
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 23:58:45

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:19', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f2f3feb6-27d4-41f6-979f-29d9e213e62d' User entered 'No (N)'	System	13 Aug 2020 23:58:45
	System	13 Aug 2020 23:58:45

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f2f3feb6-27d4-41f6-979f-29d9e213e62d' User entered 'No (N)'	System	13 Aug 2020 23:58:45
	System	13 Aug 2020 23:58:45

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f2f3feb6-27d4-41f6-979f-29d9e213e62d'	System	13 Aug 2020 23:58:45
User entered 'None (1)'	System	13 Aug 2020 23:58:45

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f2f3feb6-27d4-41f6-979f-29d9e213e62d' User entered '13 Aug 2020 19:58'	System	13 Aug 2020 23:58:45
	System	13 Aug 2020 23:58:45

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 2'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:30', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '96c182f2-cd15-41b6-ae92-4ada31b0f320'	System	14 Aug 2020 23:24:56
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 23:24:56

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:34', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '96c182f2-cd15-41b6-ae92-4ada31b0f320'	System	14 Aug 2020 23:24:56
User entered 'No (N)'	System	14 Aug 2020 23:24:56

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '96c182f2-cd15-41b6-ae92-4ada31b0f320' User entered 'No (N)'	System	14 Aug 2020 23:24:56
	System	14 Aug 2020 23:24:56

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '96c182f2-cd15-41b6-ae92-4ada31b0f320'	System	14 Aug 2020 23:24:56
User entered 'None (1)'	System	14 Aug 2020 23:24:56

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:24:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '96c182f2-cd15-41b6-ae92-4ada31b0f320'	System	14 Aug 2020 23:24:56
User entered '14 Aug 2020 19:24'	System	14 Aug 2020 23:24:56

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 3'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '70876453-b362-4bca-9ce2-bd1cc8466543'	System	15 Aug 2020 23:15:50
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 23:15:50

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '70876453-b362-4bca-9ce2-bd1cc8466543' User entered 'No (N)'	System	15 Aug 2020 23:15:50
	System	15 Aug 2020 23:15:50

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '70876453-b362-4bca-9ce2-bd1cc8466543' User entered 'No (N)'	System	15 Aug 2020 23:15:50
	System	15 Aug 2020 23:15:50

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:44', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '70876453-b362-4bca-9ce2-bd1cc8466543'	System	15 Aug 2020 23:15:50
User entered 'None (1)'	System	15 Aug 2020 23:15:50

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:48', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '70876453-b362-4bca-9ce2-bd1cc8466543' User entered '15 Aug 2020 19:15'	System	15 Aug 2020 23:15:50
	System	15 Aug 2020 23:15:50

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 4'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:13', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f55d5812-9541-491e-86b6-65961e95828d'	System	16 Aug 2020 23:43:33
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 23:43:33

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f55d5812-9541-491e-86b6-65961e95828d' User entered 'No (N)'	System	16 Aug 2020 23:43:33
	System	16 Aug 2020 23:43:33

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f55d5812-9541-491e-86b6-65961e95828d'	System	16 Aug 2020 23:43:33
User entered 'No (N)'	System	16 Aug 2020 23:43:33

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f55d5812-9541-491e-86b6-65961e95828d' User entered 'None (1)'	System	16 Aug 2020 23:43:33
	System	16 Aug 2020 23:43:33

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:30', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'f55d5812-9541-491e-86b6-65961e95828d' User entered '16 Aug 2020 19:43'	System	16 Aug 2020 23:43:33
	System	16 Aug 2020 23:43:33

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 5'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:45', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd7897992-f21f-4d75-803c-77cadf50180d' User entered 'None (1)'	System	18 Aug 2020 02:23:01
	System	18 Aug 2020 02:23:01

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:48', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd7897992-f21f-4d75-803c-77cadf50180d' User entered 'No (N)'	System	18 Aug 2020 02:23:01
	System	18 Aug 2020 02:23:01

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:50', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd7897992-f21f-4d75-803c-77cadf50180d' User entered 'No (N)'	System	18 Aug 2020 02:23:01
	System	18 Aug 2020 02:23:01

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd7897992-f21f-4d75-803c-77cadf50180d' User entered 'None (1)'	System	18 Aug 2020 02:23:01
	System	18 Aug 2020 02:23:01

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:22:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd7897992-f21f-4d75-803c-77cadf50180d' User entered '17 Aug 2020 22:22'	System	18 Aug 2020 02:23:01
	System	18 Aug 2020 02:23:01

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 6'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'cb45ec82-e526-47f6-b06d-8df7d8f732d7'	System	19 Aug 2020 00:44:28
User entered 'None (1)'	System	19 Aug 2020 00:44:28

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'cb45ec82-e526-47f6-b06d-8df7d8f732d7'	System	19 Aug 2020 00:44:28
User entered 'No (N)'	System	19 Aug 2020 00:44:28

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'cb45ec82-e526-47f6-b06d-8df7d8f732d7'	System	19 Aug 2020 00:44:28
User entered 'No (N)'	System	19 Aug 2020 00:44:28

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'cb45ec82-e526-47f6-b06d-8df7d8f732d7'	System	19 Aug 2020 00:44:28
User entered 'None (1)'	System	19 Aug 2020 00:44:28

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'cb45ec82-e526-47f6-b06d-8df7d8f732d7'	System	19 Aug 2020 00:44:28
User entered '18 Aug 2020 20:44'	System	19 Aug 2020 00:44:28

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 7'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:34', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c7459fc-5216-441c-af91-f3512e210e7e' User entered 'None (1)'	System	20 Aug 2020 02:33:49
	System	20 Aug 2020 02:33:49

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c7459fc-5216-441c-af91-f3512e210e7e' User entered 'No (N)'	System	20 Aug 2020 02:33:49
	System	20 Aug 2020 02:33:49

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c7459fc-5216-441c-af91-f3512e210e7e' User entered 'No (N)'	System	20 Aug 2020 02:33:49
	System	20 Aug 2020 02:33:49

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c7459fc-5216-441c-af91-f3512e210e7e' User entered 'None (1)'	System	20 Aug 2020 02:33:49
	System	20 Aug 2020 02:33:49

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c7459fc-5216-441c-af91-f3512e210e7e' User entered '19 Aug 2020 22:33'	System	20 Aug 2020 02:33:49
	System	20 Aug 2020 02:33:49

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:56:57', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:06', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered 'None (0)'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65'	System	13 Aug 2020 15:57:22
User entered 'No (N)'	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T11:57:19', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5bbfcede-f099-4981-97bc-ab0b68d4cb65' User entered '13 Aug 2020 11:57'	System	13 Aug 2020 15:57:22
	System	13 Aug 2020 15:57:22

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 11:54'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 14:24'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered 'None (0)'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:58:57', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68'	System	13 Aug 2020 23:59:29
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered 'None (0)'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68'	System	13 Aug 2020 23:59:29
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:13', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered 'None (0)'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:16', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered 'None (0)'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:20', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered 'No (N)'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-13T19:59:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '86ba37b6-52f4-4c6b-8ce1-e37df6425b68' User entered '13 Aug 2020 19:59'	System	13 Aug 2020 23:59:29
	System	13 Aug 2020 23:59:29

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 2'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:01', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'None (0)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d'	System	14 Aug 2020 23:25:37
User entered 'No interference with activity (1)'	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'None (0)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:19', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'None (0)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:23', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'None (0)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'None (0)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:30', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered 'No (N)'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-14T19:25:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7f5dd370-042f-43d4-b7a7-defe02bc507d' User entered '14 Aug 2020 19:25'	System	14 Aug 2020 23:25:37
	System	14 Aug 2020 23:25:37

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 3'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:15:57', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd'	System	15 Aug 2020 23:16:34
User entered 'No interference with activity (1)'	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'None (0)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'No interference with activity (1)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'None (0)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'None (0)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'None (0)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered 'No (N)'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-15T19:16:32', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c455ee71-0b0f-4562-9b13-c990792f40fd' User entered '15 Aug 2020 19:16'	System	15 Aug 2020 23:16:34
	System	15 Aug 2020 23:16:34

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 4'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'None (0)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered 'No (N)'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-16T19:43:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'dfa96809-47a7-48d8-ab2c-14dcc54744d' User entered '16 Aug 2020 19:43'	System	16 Aug 2020 23:44:01
	System	16 Aug 2020 23:44:01

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 5'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:19', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'None (0)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered 'No (N)'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-17T22:23:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0c1e3706-4a87-4de3-9663-b2669e9824ec' User entered '17 Aug 2020 22:23'	System	18 Aug 2020 02:23:26
	System	18 Aug 2020 02:23:26

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 6'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:29', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:34', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:36', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:41', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered 'None (0)'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:44', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b'	System	19 Aug 2020 00:44:51
User entered 'No (N)'	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-18T20:44:50', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a7a6b6b8-3146-42d3-8a0b-6479de27554b' User entered '18 Aug 2020 20:44'	System	19 Aug 2020 00:44:51
	System	19 Aug 2020 00:44:51

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 7'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5'	System	20 Aug 2020 02:34:17
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:33:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5'	System	20 Aug 2020 02:34:17
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:02', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered 'None (0)'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:05', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered 'None (0)'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered 'None (0)'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered 'None (0)'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered 'No (N)'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-19T22:34:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '3d39b6fe-ebfd-4a60-99a3-aa13fcc574c5' User entered '19 Aug 2020 22:34'	System	20 Aug 2020 02:34:17
	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	20 Aug 2020 02:34:17
User entered 'Day 8'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:34:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75e17a0d-6e41-4ad2-af28-c0d66be35365' User entered 'None (0)'	System	20 Aug 2020 23:34:41
	System	20 Aug 2020 23:34:41

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:34:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75e17a0d-6e41-4ad2-af28-c0d66be35365' User entered '20 Aug 2020 19:34'	System	20 Aug 2020 23:34:41
	System	20 Aug 2020 23:34:41

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	20 Aug 2020 02:34:17
User entered 'Day 8'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:34:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bad9b923-d7db-488d-97f2-e951ccc90020' User entered 'None (0)'	System	20 Aug 2020 23:34:59
	System	20 Aug 2020 23:34:59

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:34:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bad9b923-d7db-488d-97f2-e951ccc90020' User entered '20 Aug 2020 19:34'	System	20 Aug 2020 23:34:59
	System	20 Aug 2020 23:34:59

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	20 Aug 2020 02:34:17
User entered 'Day 8'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:35:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '47737a6c-ebb0-4e47-8c27-d877875fdf27'	System	20 Aug 2020 23:35:05
User entered 'No (N)'	System	20 Aug 2020 23:35:05

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-08-20T19:35:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '47737a6c-ebb0-4e47-8c27-d877875fdf27' User entered '20 Aug 2020 19:35'	System	20 Aug 2020 23:35:05
	System	20 Aug 2020 23:35:05

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 02:34:17

US3522112

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 02:34:17

US3522112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:47:19

US3522112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '20 Aug 2020'	Yaman Ahmed (b) (4)	20 Aug 2020 13:47:19

US3522112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:47:19

US3522112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Had pain day 1-4 at injection site but didn't interfere with activity and resolved. May have had several days of mild headache which did not require medication; otherwise no other changes reported'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:47:19

US3522112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:47:25

US3522112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	20 Aug 2020 13:47:25

US3522112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 17:15:58

US3522112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '27 Aug 2020'	Yaman Ahmed (b) (4)	27 Aug 2020 17:15:58

US3522112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 17:15:58

US3522112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk'	Yaman Ahmed (b) (4)	27 Aug 2020 17:15:58

US3522112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 17:16:03

US3522112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	27 Aug 2020 17:16:03

US3522112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:55:46

US3522112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:55:46

US3522112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:55:46

US3522112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: New Information	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:56:17
User entered 'Subject reported no new symptoms or Adverse Events'	(b) (4), (b) (6)	03 Sep 2020 17:55:46

US3522112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:55:52

US3522112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	03 Sep 2020 17:55:52

US3522112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:38:52

US3522112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:38:52

US3522112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:38:52

US3522112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'VISIT2'	System	10 Sep 2020 14:38:52

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '10:34'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '10 Sep 2020 10:34'	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '108'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'bpm'	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '18'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'breaths/min'	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '148'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '96'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 15:37:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:37:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 14:39:37
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '11:24' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '10 Sep 2020 11:24'	System	10 Sep 2020 15:37:22
User entered empty.	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'bpm'	System	10 Sep 2020 15:37:22
User entered empty.	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '16' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'breaths/min'	System	10 Sep 2020 15:37:22
User entered empty.	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	10 Sep 2020 15:37:22
User entered empty.	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:37:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	10 Sep 2020 15:37:22
User entered empty.	System	10 Sep 2020 14:39:37

US3522112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:47

US3522112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:39:47

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10:54'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '10 Sep 2020 10:54'	System	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'ONCE'	System	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:02:54

US3522112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:12

US3522112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:12

US3522112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10:40'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:12

US3522112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '10 Sep 2020 10:40'	System	10 Sep 2020 15:03:12

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '10:43'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '10 Sep 2020 10:43'	System	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered empty.	System	10 Sep 2020 15:03:27

US3522112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:03:33

US3522112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '1'	System	10 Sep 2020 15:03:33

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:24:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1c3e0db3-4152-45c5-b648-e1c4618be315' User entered 'Yes (Y)'	System	10 Sep 2020 15:24:40
	System	10 Sep 2020 15:24:40

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:24:29', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1c3e0db3-4152-45c5-b648-e1c4618be315' User entered '98.1'	System	10 Sep 2020 15:24:40
	System	10 Sep 2020 15:24:40

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:24:33', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1c3e0db3-4152-45c5-b648-e1c4618be315' User entered 'No (N)'	System	10 Sep 2020 15:24:40
	System	10 Sep 2020 15:24:40

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:24:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1c3e0db3-4152-45c5-b648-e1c4618be315' User entered '10 Sep 2020 11:24'	System	10 Sep 2020 15:24:40
	System	10 Sep 2020 15:24:40

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 11:14'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 13:44'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:21:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2ae5c326-d174-4804-a4b2-7083bc844319' User entered 'Yes (Y)'	System	10 Sep 2020 21:22:19
	System	10 Sep 2020 21:22:19

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:22:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2ae5c326-d174-4804-a4b2-7083bc844319' User entered '96.9'	System	10 Sep 2020 21:22:19
	System	10 Sep 2020 21:22:19

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:22:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2ae5c326-d174-4804-a4b2-7083bc844319' User entered 'No (N)'	System	10 Sep 2020 21:22:19
	System	10 Sep 2020 21:22:19

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:22:13', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2ae5c326-d174-4804-a4b2-7083bc844319' User entered '10 Sep 2020 17:22'	System	10 Sep 2020 21:22:19
	System	10 Sep 2020 21:22:19

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 14:39'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 2'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:12:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c708513-3721-41c2-904e-b93662fdbda2' User entered 'Yes (Y)'	System	11 Sep 2020 22:13:12
	System	11 Sep 2020 22:13:12

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:12:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c708513-3721-41c2-904e-b93662fdbda2' User entered '98.7'	System	11 Sep 2020 22:13:12
	System	11 Sep 2020 22:13:12

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:12:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c708513-3721-41c2-904e-b93662fdbda2' User entered 'No (N)'	System	11 Sep 2020 22:13:12
	System	11 Sep 2020 22:13:12

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:12:48', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5c708513-3721-41c2-904e-b93662fdbda2'	System	11 Sep 2020 22:13:12
User entered '11 Sep 2020 18:12'	System	11 Sep 2020 22:13:12

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 3'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:01:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '07b385dc-7384-478d-8c61-d5f0a03b314b' User entered 'Yes (Y)'	System	12 Sep 2020 21:02:55
	System	12 Sep 2020 21:02:55

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:02:41', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '07b385dc-7384-478d-8c61-d5f0a03b314b' User entered '98.5'	System	12 Sep 2020 21:02:55
	System	12 Sep 2020 21:02:55

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:02:45', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '07b385dc-7384-478d-8c61-d5f0a03b314b' User entered 'No (N)'	System	12 Sep 2020 21:02:55
	System	12 Sep 2020 21:02:55

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:02:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '07b385dc-7384-478d-8c61-d5f0a03b314b' User entered '12 Sep 2020 17:02'	System	12 Sep 2020 21:02:55
	System	12 Sep 2020 21:02:55

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 4'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T16:57:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fc72f672-ae9f-4704-924c-dc5e42448ccd' User entered 'Yes (Y)'	System	13 Sep 2020 21:00:03
	System	13 Sep 2020 21:00:03

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T16:59:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fc72f672-ae9f-4704-924c-dc5e42448ccd' User entered '96.2'	System	13 Sep 2020 21:00:03
	System	13 Sep 2020 21:00:03

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T16:59:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fc72f672-ae9f-4704-924c-dc5e42448ccd' User entered 'No (N)'	System	13 Sep 2020 21:00:03
	System	13 Sep 2020 21:00:03

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T16:59:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fc72f672-ae9f-4704-924c-dc5e42448ccd' User entered '13 Sep 2020 16:59'	System	13 Sep 2020 21:00:03
	System	13 Sep 2020 21:00:03

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 5'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5a2b982e-b786-4795-8601-8de591a9e667' User entered 'Yes (Y)'	System	14 Sep 2020 22:23:24
	System	14 Sep 2020 22:23:24

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5a2b982e-b786-4795-8601-8de591a9e667' User entered '97.2'	System	14 Sep 2020 22:23:24
	System	14 Sep 2020 22:23:24

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5a2b982e-b786-4795-8601-8de591a9e667'	System	14 Sep 2020 22:23:24
User entered 'No (N)'	System	14 Sep 2020 22:23:24

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5a2b982e-b786-4795-8601-8de591a9e667' User entered '14 Sep 2020 18:23'	System	14 Sep 2020 22:23:24
	System	14 Sep 2020 22:23:24

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 6'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '8e9b509f-5abb-48ed-b5b6-f4843179e8b0' User entered 'Yes (Y)'	System	15 Sep 2020 21:12:27
	System	15 Sep 2020 21:12:27

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '8e9b509f-5abb-48ed-b5b6-f4843179e8b0' User entered '98.4'	System	15 Sep 2020 21:12:27
	System	15 Sep 2020 21:12:27

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:20', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '8e9b509f-5abb-48ed-b5b6-f4843179e8b0'	System	15 Sep 2020 21:12:27
User entered 'No (N)'	System	15 Sep 2020 21:12:27

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '8e9b509f-5abb-48ed-b5b6-f4843179e8b0' User entered '15 Sep 2020 17:12'	System	15 Sep 2020 21:12:27
	System	15 Sep 2020 21:12:27

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 7'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:23:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '89e64295-7c40-48e3-8f63-4fcf63b2632e' User entered 'Yes (Y)'	System	16 Sep 2020 22:25:33
	System	16 Sep 2020 22:25:33

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:13', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '89e64295-7c40-48e3-8f63-4fcf63b2632e' User entered '98.7'	System	16 Sep 2020 22:25:33
	System	16 Sep 2020 22:25:33

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '89e64295-7c40-48e3-8f63-4fcf63b2632e' User entered 'No (N)'	System	16 Sep 2020 22:25:33
	System	16 Sep 2020 22:25:33

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '89e64295-7c40-48e3-8f63-4fcf63b2632e' User entered '16 Sep 2020 18:25'	System	16 Sep 2020 22:25:33
	System	16 Sep 2020 22:25:33

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '53ec7c5c-0d1a-446e-adc4-a732804b933d' User entered 'None (1)'	System	10 Sep 2020 15:14:51
	System	10 Sep 2020 15:14:51

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:29', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '53ec7c5c-0d1a-446e-adc4-a732804b933d' User entered 'No (N)'	System	10 Sep 2020 15:14:51
	System	10 Sep 2020 15:14:51

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:33', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '53ec7c5c-0d1a-446e-adc4-a732804b933d' User entered 'No (N)'	System	10 Sep 2020 15:14:51
	System	10 Sep 2020 15:14:51

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '53ec7c5c-0d1a-446e-adc4-a732804b933d' User entered 'None (1)'	System	10 Sep 2020 15:14:51
	System	10 Sep 2020 15:14:51

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '53ec7c5c-0d1a-446e-adc4-a732804b933d' User entered '10 Sep 2020 11:14'	System	10 Sep 2020 15:14:51
	System	10 Sep 2020 15:14:51

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 11:14'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 13:44'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:18:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '672a3d6a-8abe-458c-94de-bf23a9fd927f' User entered 'None (1)'	System	10 Sep 2020 21:19:13
	System	10 Sep 2020 21:19:13

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:18:50', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '672a3d6a-8abe-458c-94de-bf23a9fd927f' User entered 'No (N)'	System	10 Sep 2020 21:19:13
	System	10 Sep 2020 21:19:13

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:18:56', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '672a3d6a-8abe-458c-94de-bf23a9fd927f' User entered 'No (N)'	System	10 Sep 2020 21:19:13
	System	10 Sep 2020 21:19:13

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '672a3d6a-8abe-458c-94de-bf23a9fd927f' User entered 'None (1)'	System	10 Sep 2020 21:19:13
	System	10 Sep 2020 21:19:13

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '672a3d6a-8abe-458c-94de-bf23a9fd927f' User entered '10 Sep 2020 17:19'	System	10 Sep 2020 21:19:13
	System	10 Sep 2020 21:19:13

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 14:39'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 2'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:13:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:13:23', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered 'No (N)'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered 'Yes (Y)'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:22', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered '4'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:37', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:44', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '75cfabcf-bbfb-4a13-89a6-523d1fd7f548'	System	11 Sep 2020 22:14:52
User entered '11 Sep 2020 18:14'	System	11 Sep 2020 22:14:52

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 3'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:02', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a749f273-53f1-489c-a3ca-e86641b8399c'	System	12 Sep 2020 21:03:28
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 21:03:28

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:06', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a749f273-53f1-489c-a3ca-e86641b8399c' User entered 'No (N)'	System	12 Sep 2020 21:03:28
	System	12 Sep 2020 21:03:28

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a749f273-53f1-489c-a3ca-e86641b8399c' User entered 'No (N)'	System	12 Sep 2020 21:03:28
	System	12 Sep 2020 21:03:28

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:22', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a749f273-53f1-489c-a3ca-e86641b8399c'	System	12 Sep 2020 21:03:28
User entered 'None (1)'	System	12 Sep 2020 21:03:28

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a749f273-53f1-489c-a3ca-e86641b8399c'	System	12 Sep 2020 21:03:28
User entered '12 Sep 2020 17:03'	System	12 Sep 2020 21:03:28

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 4'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '41e9dc8c-558c-46b1-afa6-22e424563f6f'	System	13 Sep 2020 21:00:32
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 21:00:32

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '41e9dc8c-558c-46b1-afa6-22e424563f6f' User entered 'No (N)'	System	13 Sep 2020 21:00:32
	System	13 Sep 2020 21:00:32

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '41e9dc8c-558c-46b1-afa6-22e424563f6f' User entered 'No (N)'	System	13 Sep 2020 21:00:32
	System	13 Sep 2020 21:00:32

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '41e9dc8c-558c-46b1-afa6-22e424563f6f' User entered 'None (1)'	System	13 Sep 2020 21:00:32
	System	13 Sep 2020 21:00:32

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:27', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '41e9dc8c-558c-46b1-afa6-22e424563f6f' User entered '13 Sep 2020 17:00'	System	13 Sep 2020 21:00:32
	System	13 Sep 2020 21:00:32

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 5'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:29', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7222fd33-ef0a-47a3-94a4-504811d5ec2d'	System	14 Sep 2020 22:23:47
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 22:23:47

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:32', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7222fd33-ef0a-47a3-94a4-504811d5ec2d' User entered 'No (N)'	System	14 Sep 2020 22:23:47
	System	14 Sep 2020 22:23:47

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7222fd33-ef0a-47a3-94a4-504811d5ec2d' User entered 'No (N)'	System	14 Sep 2020 22:23:47
	System	14 Sep 2020 22:23:47

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7222fd33-ef0a-47a3-94a4-504811d5ec2d' User entered 'None (1)'	System	14 Sep 2020 22:23:47
	System	14 Sep 2020 22:23:47

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:44', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7222fd33-ef0a-47a3-94a4-504811d5ec2d' User entered '14 Sep 2020 18:23'	System	14 Sep 2020 22:23:47
	System	14 Sep 2020 22:23:47

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 6'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aefc65d-d92b-4b83-b991-de6783422ec7' User entered 'None (1)'	System	15 Sep 2020 21:13:00
	System	15 Sep 2020 21:13:00

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aefc65d-d92b-4b83-b991-de6783422ec7' User entered 'No (N)'	System	15 Sep 2020 21:13:00
	System	15 Sep 2020 21:13:00

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aefc65d-d92b-4b83-b991-de6783422ec7' User entered 'No (N)'	System	15 Sep 2020 21:13:00
	System	15 Sep 2020 21:13:00

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aefc65d-d92b-4b83-b991-de6783422ec7' User entered 'None (1)'	System	15 Sep 2020 21:13:00
	System	15 Sep 2020 21:13:00

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:12:56', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aefc65d-d92b-4b83-b991-de6783422ec7' User entered '15 Sep 2020 17:12'	System	15 Sep 2020 21:13:00
	System	15 Sep 2020 21:13:00

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 7'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '193ed950-9d3f-49bb-bd0f-f525b2f56e61'	System	16 Sep 2020 22:25:59
User entered 'None (1)'	System	16 Sep 2020 22:25:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:43', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '193ed950-9d3f-49bb-bd0f-f525b2f56e61' User entered 'No (N)'	System	16 Sep 2020 22:25:59
	System	16 Sep 2020 22:25:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '193ed950-9d3f-49bb-bd0f-f525b2f56e61' User entered 'No (N)'	System	16 Sep 2020 22:25:59
	System	16 Sep 2020 22:25:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '193ed950-9d3f-49bb-bd0f-f525b2f56e61'	System	16 Sep 2020 22:25:59
User entered 'None (1)'	System	16 Sep 2020 22:25:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:25:56', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '193ed950-9d3f-49bb-bd0f-f525b2f56e61'	System	16 Sep 2020 22:25:59
User entered '16 Sep 2020 18:25'	System	16 Sep 2020 22:25:59

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'None (0)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:14:59', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a'	System	10 Sep 2020 15:15:24
User entered 'No interference with activity (1)'	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'None (0)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:07', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'None (0)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'None (0)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'None (0)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:16', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered 'No (N)'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T11:15:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '67d57f76-d527-460c-b6e0-b70ee57bea9a' User entered '10 Sep 2020 11:15'	System	10 Sep 2020 15:15:24
	System	10 Sep 2020 15:15:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 11:14'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 13:44'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:19:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:21:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'None (0)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:21:42', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered 'No (N)'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-10T17:21:45', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '142e8bb8-00c2-47ab-a61d-8d97627fd7cb' User entered '10 Sep 2020 17:21'	System	10 Sep 2020 21:21:49
	System	10 Sep 2020 21:21:49

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '10 Sep 2020 14:39'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 2'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3'	System	11 Sep 2020 22:15:32
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:14:59', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3'	System	11 Sep 2020 22:15:32
User entered 'Some interference with activity (2)'	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:06', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3'	System	11 Sep 2020 22:15:32
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3' User entered 'None (0)'	System	11 Sep 2020 22:15:32
	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3' User entered 'None (0)'	System	11 Sep 2020 22:15:32
	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3' User entered 'None (0)'	System	11 Sep 2020 22:15:32
	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3' User entered 'No (N)'	System	11 Sep 2020 22:15:32
	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-11T18:15:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b62ed38f-a6e0-4c36-a65f-22343248cdd3'	System	11 Sep 2020 22:15:32
User entered '11 Sep 2020 18:15'	System	11 Sep 2020 22:15:32

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 3'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:42', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:45', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'None (0)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered 'No (N)'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-12T17:03:54', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '5ee6346d-b193-4368-8830-721ba30d184c' User entered '12 Sep 2020 17:03'	System	12 Sep 2020 21:03:57
	System	12 Sep 2020 21:03:57

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 4'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:34', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:39', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:44', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:00:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'None (0)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:01:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered 'No (N)'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-13T17:01:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '37cfdad7-33ad-4817-8f91-e0d6b24ce827' User entered '13 Sep 2020 17:01'	System	13 Sep 2020 21:01:07
	System	13 Sep 2020 21:01:07

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 5'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:23:59', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:24:01', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:24:05', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'None (0)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:24:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered 'No (N)'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-14T18:24:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '29f66306-41d0-42a8-bce2-1d1ed59afbad' User entered '14 Sep 2020 18:24'	System	14 Sep 2020 22:24:13
	System	14 Sep 2020 22:24:13

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 6'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:06', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:13', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'None (0)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:18', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered 'No (N)'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-15T17:13:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'c11dbefa-c7b8-4e6c-bd5e-3e40aae51b1b' User entered '15 Sep 2020 17:13'	System	15 Sep 2020 21:13:24
	System	15 Sep 2020 21:13:24

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	10 Sep 2020 15:02:54
User entered 'Day 7'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:05', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:11', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:16', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'None (0)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:22', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered 'No (N)'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-09-16T18:26:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '756158a0-b8d5-4b63-9389-d6a5b6ff46ab' User entered '16 Sep 2020 18:26'	System	16 Sep 2020 22:26:31
	System	16 Sep 2020 22:26:31

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:02:54

US3522112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:02:54

US3522112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:36

US3522112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:36

US3522112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:36

US3522112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Day 1-2 post visit 2 slight arm soreness and bump. Nothing since then. No med changes, vaccines, COVID exposure, medication change, pregnancy risk.'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:36

US3522112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:45

US3522112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	17 Sep 2020 18:23:45

US3522112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	Kristin Eis (b) (4)	24 Sep 2020 16:53:15

US3522112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '24 Sep 2020'	Kristin Eis (b) (4)	24 Sep 2020 16:53:15

US3522112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	Kristin Eis (b) (4)	24 Sep 2020 16:53:15

US3522112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	Kristin Eis (b) (4)	24 Sep 2020 16:53:15

US3522112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	Kristin Eis (b) (4)	24 Sep 2020 16:53:23

US3522112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	24 Sep 2020 16:53:23

US3522112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:18

US3522112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:18

US3522112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:18

US3522112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:18

US3522112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:35

US3522112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	01 Oct 2020 14:07:35

US3522112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:13:27

US3522112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:13:27

US3522112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:13:27

US3522112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'VISIT3'	System	07 Oct 2020 17:13:27

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '13:08'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '7 Oct 2020 13:08'	System	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '114'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'bpm'	System	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '18'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'breaths/min'	System	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '140'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '82'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'mmHg'	System	07 Oct 2020 17:14:46

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59

US3522112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59

US3522112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:15:00

US3522112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:15:00

US3522112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:24:26

US3522112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:24:26

US3522112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered '13:19'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:24:26

US3522112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered '7 Oct 2020 13:19'	System	07 Oct 2020 17:24:26

US3522112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:24:32

US3522112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	07 Oct 2020 17:24:32

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 64'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-13T10:01:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aad90e1-7f5c-4071-a54f-ddafce380cde'	System	13 Oct 2020 14:02:12
User entered 'No (N)'	System	13 Oct 2020 14:02:12

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-13T10:01:52', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aad90e1-7f5c-4071-a54f-ddafce380cde'	System	13 Oct 2020 14:02:12
User entered 'No (N)'	System	13 Oct 2020 14:02:12

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-13T10:02:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '1aad90e1-7f5c-4071-a54f-ddafce380cde' User entered '13 Oct 2020 10:02:08'	System	13 Oct 2020 14:02:12
	System	13 Oct 2020 14:02:12

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 71'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-20T08:45:15', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '21843afe-ef99-480f-af0b-3f7b13576d2f' User entered 'No (N)'	System	20 Oct 2020 12:45:31
	System	20 Oct 2020 12:45:31

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-20T08:45:23', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '21843afe-ef99-480f-af0b-3f7b13576d2f' User entered 'No (N)'	System	20 Oct 2020 12:45:31
	System	20 Oct 2020 12:45:31

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-20T08:45:28', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '21843afe-ef99-480f-af0b-3f7b13576d2f' User entered '20 Oct 2020 08:45:28'	System	20 Oct 2020 12:45:31
	System	20 Oct 2020 12:45:31

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 78'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-27T11:16:04', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0a52e42d-9541-40e4-8139-f0e10ea82e7a' User entered 'No (N)'	System	27 Oct 2020 15:16:15
	System	27 Oct 2020 15:16:15

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-27T11:16:08', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0a52e42d-9541-40e4-8139-f0e10ea82e7a' User entered 'No (N)'	System	27 Oct 2020 15:16:15
	System	27 Oct 2020 15:16:15

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-10-27T11:16:12', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '0a52e42d-9541-40e4-8139-f0e10ea82e7a' User entered '27 Oct 2020 11:16:12'	System	27 Oct 2020 15:16:15
	System	27 Oct 2020 15:16:15

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 92'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-10T12:11:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '265d7044-402a-4ac7-9050-0df11346eea3' User entered 'No (N)'	System	10 Nov 2020 17:11:40
	System	10 Nov 2020 17:11:40

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-10T12:11:33', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '265d7044-402a-4ac7-9050-0df11346eea3' User entered 'No (N)'	System	10 Nov 2020 17:11:40
	System	10 Nov 2020 17:11:40

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-10T12:11:38', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '265d7044-402a-4ac7-9050-0df11346eea3' User entered '10 Nov 2020 12:11:38'	System	10 Nov 2020 17:11:40
	System	10 Nov 2020 17:11:40

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered 'Day 99'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-17T11:21:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '964001c3-8c26-4f6f-a227-dc852a1c8222'	System	17 Nov 2020 16:21:47
User entered 'No (N)'	System	17 Nov 2020 16:21:47

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-17T11:21:34', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '964001c3-8c26-4f6f-a227-dc852a1c8222'	System	17 Nov 2020 16:21:47
User entered 'No (N)'	System	17 Nov 2020 16:21:47

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-17T11:21:42', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '964001c3-8c26-4f6f-a227-dc852a1c8222' User entered '17 Nov 2020 11:21:42'	System	17 Nov 2020 16:21:47
	System	17 Nov 2020 16:21:47

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 15:37:03

US3522112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:59:17
Data entry locked.	System	13 Aug 2020 15:37:03
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 15:37:03

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-21T09:44:49', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd079354c-d85f-4da6-9785-77ac9cd088ff' User entered 'No (N)'	System	21 Nov 2020 14:45:04
	System	21 Nov 2020 14:45:04

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-21T09:44:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd079354c-d85f-4da6-9785-77ac9cd088ff' User entered 'No (N)'	System	21 Nov 2020 14:45:04
	System	21 Nov 2020 14:45:04

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-21T09:44:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'd079354c-d85f-4da6-9785-77ac9cd088ff' User entered '21 Nov 2020 09:44:58'	System	21 Nov 2020 14:45:04
	System	21 Nov 2020 14:45:04

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-28T08:32:14', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b00d92cc-648b-428e-b1bc-89ec2dc92155'	System	28 Nov 2020 13:32:35
User entered 'No (N)'	System	28 Nov 2020 13:32:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-28T08:32:24', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b00d92cc-648b-428e-b1bc-89ec2dc92155'	System	28 Nov 2020 13:32:35
User entered 'No (N)'	System	28 Nov 2020 13:32:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-11-28T08:32:31', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b00d92cc-648b-428e-b1bc-89ec2dc92155' User entered '28 Nov 2020 08:32:31'	System	28 Nov 2020 13:32:35
	System	28 Nov 2020 13:32:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-05T10:12:17', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7402e843-34f7-4c9e-9f1a-b0a9ef9f9c5d' User entered 'No (N)'	System	05 Dec 2020 15:12:38
	System	05 Dec 2020 15:12:38

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-05T10:12:29', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7402e843-34f7-4c9e-9f1a-b0a9ef9f9c5d'	System	05 Dec 2020 15:12:38
User entered 'No (N)'	System	05 Dec 2020 15:12:38

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-05T10:12:32', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7402e843-34f7-4c9e-9f1a-b0a9ef9f9c5d' User entered '05 Dec 2020 10:12:32'	System	05 Dec 2020 15:12:38
	System	05 Dec 2020 15:12:38

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-12T09:13:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7b53b9d4-43c0-4484-bd3a-bff8bb2d8931'	System	12 Dec 2020 14:14:12
User entered 'No (N)'	System	12 Dec 2020 14:14:12

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-12T09:14:06', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7b53b9d4-43c0-4484-bd3a-bff8bb2d8931'	System	12 Dec 2020 14:14:12
User entered 'No (N)'	System	12 Dec 2020 14:14:12

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-12T09:14:09', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '7b53b9d4-43c0-4484-bd3a-bff8bb2d8931' User entered '12 Dec 2020 09:14:09'	System	12 Dec 2020 14:14:12
	System	12 Dec 2020 14:14:12

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-19T09:49:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9ae52fcb-c228-4e29-bd07-bb0b3c42a8bf' User entered 'No (N)'	System	19 Dec 2020 14:49:42
	System	19 Dec 2020 14:49:42

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-19T09:49:32', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9ae52fcb-c228-4e29-bd07-bb0b3c42a8bf' User entered 'No (N)'	System	19 Dec 2020 14:49:42

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-19T09:49:40', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9ae52fcb-c228-4e29-bd07-bb0b3c42a8bf' User entered '19 Dec 2020 09:49:40'	System	19 Dec 2020 14:49:42
	System	19 Dec 2020 14:49:42

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-26T09:14:47', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ae95924c-763d-404b-8c7a-d81f9bb0e1c3' User entered 'No (N)'	System	26 Dec 2020 14:15:02
	System	26 Dec 2020 14:15:02

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-26T09:14:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ae95924c-763d-404b-8c7a-d81f9bb0e1c3' User entered 'No (N)'	System	26 Dec 2020 14:15:02
	System	26 Dec 2020 14:15:02

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2020-12-26T09:14:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ae95924c-763d-404b-8c7a-d81f9bb0e1c3' User entered '26 Dec 2020 09:14:58'	System	26 Dec 2020 14:15:02
	System	26 Dec 2020 14:15:02

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2021-01-02T13:30:58', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ef5fdb7-73e8-4c9f-9a3c-d3e2942665ec' User entered 'No (N)'	System	02 Jan 2021 18:31:18
	System	02 Jan 2021 18:31:18

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2021-01-02T13:31:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ef5fdb7-73e8-4c9f-9a3c-d3e2942665ec'	System	02 Jan 2021 18:31:18
User entered 'No (N)'	System	02 Jan 2021 18:31:18

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14A63545-51A3-4C5A-9CA2-4ECA2F2FAFED0)', Time: '2021-01-02T13:31:16', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ef5fdb7-73e8-4c9f-9a3c-d3e2942665ec' User entered '02 Jan 2021 13:31:16'	System	02 Jan 2021 18:31:18
	System	02 Jan 2021 18:31:18

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-16T11:05:45', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '253f81b4-ca04-4d1f-8822-8909f5b6e73f' User entered 'No (N)'	System	16 Jan 2021 16:05:58
	System	16 Jan 2021 16:05:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-16T11:05:51', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '253f81b4-ca04-4d1f-8822-8909f5b6e73f' User entered 'No (N)'	System	16 Jan 2021 16:05:58
	System	16 Jan 2021 16:05:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-16T11:05:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '253f81b4-ca04-4d1f-8822-8909f5b6e73f' User entered '16 Jan 2021 11:05:55'	System	16 Jan 2021 16:05:58
	System	16 Jan 2021 16:05:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-23T11:26:35', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9041e977-b052-4a93-8deb-ba2f6ffb6179' User entered 'No (N)'	System	25 Jan 2021 21:46:22
	System	25 Jan 2021 21:46:22

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-23T11:26:42', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9041e977-b052-4a93-8deb-ba2f6ffb6179' User entered 'No (N)'	System	25 Jan 2021 21:46:22

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-23T11:26:46', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '9041e977-b052-4a93-8deb-ba2f6ffb6179' User entered '23 Jan 2021 11:26:46'	System	25 Jan 2021 21:46:22

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-30T12:25:10', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b1db1e29-b208-4d13-8fa1-c00c2a5b760d' User entered 'No (N)'	System	03 Feb 2021 16:04:48
	System	03 Feb 2021 16:04:48

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-30T12:25:21', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b1db1e29-b208-4d13-8fa1-c00c2a5b760d' User entered 'No (N)'	System	03 Feb 2021 16:04:48

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-01-30T12:25:25', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'b1db1e29-b208-4d13-8fa1-c00c2a5b760d' User entered '30 Jan 2021 12:25:25'	System	03 Feb 2021 16:04:48
	System	03 Feb 2021 16:04:48

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-06T09:20:26', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bf63f830-4615-4608-8607-0ad3c38511fa' User entered 'No (N)'	System	06 Feb 2021 14:20:39
	System	06 Feb 2021 14:20:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-06T09:20:32', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bf63f830-4615-4608-8607-0ad3c38511fa' User entered 'No (N)'	System	06 Feb 2021 14:20:39
	System	06 Feb 2021 14:20:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-06T09:20:36', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bf63f830-4615-4608-8607-0ad3c38511fa' User entered '06 Feb 2021 09:20:36'	System	06 Feb 2021 14:20:39
	System	06 Feb 2021 14:20:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-13T09:35:53', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ddbda039-56fd-4c79-9496-c2b7abc29098' User entered 'No (N)'	System	13 Feb 2021 14:36:33
	System	13 Feb 2021 14:36:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-13T09:35:56', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ddbda039-56fd-4c79-9496-c2b7abc29098' User entered 'No (N)'	System	13 Feb 2021 14:36:33
	System	13 Feb 2021 14:36:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-13T09:35:59', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'ddbda039-56fd-4c79-9496-c2b7abc29098' User entered '13 Feb 2021 09:35:59'	System	13 Feb 2021 14:36:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-20T09:12:55', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a55c4b54-db97-45df-94ab-b5f87165d51d' User entered 'No (N)'	System	24 Feb 2021 18:28:58
	System	24 Feb 2021 18:28:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-20T09:12:59', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a55c4b54-db97-45df-94ab-b5f87165d51d' User entered 'No (N)'	System	24 Feb 2021 18:28:58
	System	24 Feb 2021 18:28:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-20T09:13:03', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a55c4b54-db97-45df-94ab-b5f87165d51d' User entered '20 Feb 2021 09:13:03'	System	24 Feb 2021 18:28:58
	System	24 Feb 2021 18:28:58

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-27T10:49:36-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a59e88e3-9e52-48c8-8570-ca6f2d93af54'	System	27 Feb 2021 15:50:10
User entered 'No (N)'	System	27 Feb 2021 15:50:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-27T10:49:42-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a59e88e3-9e52-48c8-8570-ca6f2d93af54'	System	27 Feb 2021 15:50:10
User entered 'No (N)'	System	27 Feb 2021 15:50:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-27T10:49:46-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'a59e88e3-9e52-48c8-8570-ca6f2d93af54'	System	27 Feb 2021 15:50:10
User entered '27 Feb 2021 15:49:46'	System	27 Feb 2021 15:50:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-06T08:31:53-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '211ed53c-3d32-43d2-8534-157ff98c546d' User entered 'No (N)'	System	06 Mar 2021 13:32:10
	System	06 Mar 2021 13:32:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-06T08:32:01-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '211ed53c-3d32-43d2-8534-157ff98c546d' User entered 'No (N)'	System	06 Mar 2021 13:32:10
	System	06 Mar 2021 13:32:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-06T08:32:06-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '211ed53c-3d32-43d2-8534-157ff98c546d' User entered '06 Mar 2021 08:32:06'	System	06 Mar 2021 13:32:10
	System	06 Mar 2021 13:32:10

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-13T07:09:55-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2d4def87-1e24-4e68-8f93-6bcb08765340'	System	13 Mar 2021 12:10:23
User entered 'No (N)'	System	13 Mar 2021 12:10:23

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-13T07:10:05-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2d4def87-1e24-4e68-8f93-6bcb08765340'	System	13 Mar 2021 12:10:23
User entered 'No (N)'	System	13 Mar 2021 12:10:23

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-13T07:10:21-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '2d4def87-1e24-4e68-8f93-6bcb08765340'	System	13 Mar 2021 12:10:23
User entered '13 Mar 2021 07:10:21'	System	13 Mar 2021 12:10:23

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-20T10:02:06-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6dad656c-382e-4764-9539-e8d3a9f1d4b3'	System	20 Mar 2021 14:02:20
User entered 'No (N)'	System	20 Mar 2021 14:02:20

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-20T10:02:10-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6dad656c-382e-4764-9539-e8d3a9f1d4b3'	System	20 Mar 2021 14:02:20
User entered 'No (N)'	System	20 Mar 2021 14:02:20

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-20T10:02:17-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '6dad656c-382e-4764-9539-e8d3a9f1d4b3' User entered '20 Mar 2021 10:02:17'	System	20 Mar 2021 14:02:20
	System	20 Mar 2021 14:02:20

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-27T09:21:17-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'be49fe4f-7140-4e3d-807a-33c9eb5695cd' User entered 'No (N)'	System	03 Apr 2021 13:01:39
	System	03 Apr 2021 13:01:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-27T09:21:25-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'be49fe4f-7140-4e3d-807a-33c9eb5695cd' User entered 'No (N)'	System	03 Apr 2021 13:01:39
	System	03 Apr 2021 13:01:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-03-27T09:21:30-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'be49fe4f-7140-4e3d-807a-33c9eb5695cd' User entered '27 Mar 2021 09:21:30'	System	03 Apr 2021 13:01:39
	System	03 Apr 2021 13:01:39

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-03T09:01:45-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '16b0b471-ff04-40b4-9c90-71c87bd6a73d'	System	07 Apr 2021 17:37:01
User entered 'No (N)'	System	07 Apr 2021 17:37:01

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-03T09:01:56-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '16b0b471-ff04-40b4-9c90-71c87bd6a73d'	System	07 Apr 2021 17:37:01
User entered 'No (N)'	System	07 Apr 2021 17:37:01

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-03T09:02:03-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '16b0b471-ff04-40b4-9c90-71c87bd6a73d'	System	07 Apr 2021 17:37:01
User entered '03 Apr 2021 09:02:03'	System	07 Apr 2021 17:37:01

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-10T08:21:05-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fa0f8421-4f94-46df-9ebd-762f75ceaf08'	System	10 Apr 2021 12:21:35
User entered 'No (N)'	System	10 Apr 2021 12:21:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-10T08:21:15-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fa0f8421-4f94-46df-9ebd-762f75ceaf08'	System	10 Apr 2021 12:21:35
User entered 'No (N)'	System	10 Apr 2021 12:21:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-10T08:21:22-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'fa0f8421-4f94-46df-9ebd-762f75ceaf08'	System	10 Apr 2021 12:21:35
User entered '10 Apr 2021 08:21:22'	System	10 Apr 2021 12:21:35

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:01-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef'	System	17 Apr 2021 12:31:06
User entered 'Yes (Y)'	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:10-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef' User entered 'No (N)'	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:19-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef'	System	17 Apr 2021 12:31:06
User entered 'No (N)'	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:29-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef' User entered 'Yes (Y)'	System	17 Apr 2021 12:31:06
	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Please 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:45-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef'	System	17 Apr 2021 12:31:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-17T08:30:54-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'e82a72f0-6a59-452b-a693-69c7443629ef' User entered '17 Apr 2021 08:30:54'	System	17 Apr 2021 12:31:06
	System	17 Apr 2021 12:31:06

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:38:48-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c' User entered 'Yes (Y)'	System	24 Apr 2021 13:39:40
	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:38:55-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c' User entered 'No (N)'	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:39:01-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c' User entered 'No (N)'	System	24 Apr 2021 13:39:40
	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:39:09-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c' User entered 'Yes (Y)'	System	24 Apr 2021 13:39:40
	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Please 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:39:18-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c'	System	24 Apr 2021 13:39:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-04-24T09:39:24-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '185dea70-2445-475a-a75b-c66de0a0365c' User entered '24 Apr 2021 09:39:24'	System	24 Apr 2021 13:39:40
	System	24 Apr 2021 13:39:40

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-05-01T10:27:25-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '80405504-b799-4fb8-bf78-4c1875b3b90e'	System	01 May 2021 14:27:33
User entered 'No (N)'	System	01 May 2021 14:27:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Have you been exposed to someone with 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 (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-05-01T10:27:28-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '80405504-b799-4fb8-bf78-4c1875b3b90e'	System	01 May 2021 14:27:33
User entered 'No (N)'	System	01 May 2021 14:27:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-05-01T10:27:31-04:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: '80405504-b799-4fb8-bf78-4c1875b3b90e' User entered '01 May 2021 10:27:31'	System	01 May 2021 14:27:33
	System	01 May 2021 14:27:33

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:49:45

US3522112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:49:45
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:49:45

US3522112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:55:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-27T10:49:57-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bed82f14-77db-496a-82c3-dfbc4b912ba5'	System	27 Feb 2021 15:50:14
User entered 'No (N)'	System	27 Feb 2021 15:50:14

US3522112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:55:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DFCE2879-381F-4F68-B9A0-26F9912C9CB1)', Time: '2021-02-27T10:50:05-05:00', User OID: 'PatientReportedOutcome (US3522112)', ODM File OID: 'bed82f14-77db-496a-82c3-dfbc4b912ba5'	System	27 Feb 2021 15:50:14
User entered '27 Feb 2021 15:50:05'	System	27 Feb 2021 15:50:14

US3522112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:24

US3522112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:24

US3522112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:24

US3522112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:24

US3522112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:28

US3522112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:59
User entered 'I'	System	05 Nov 2020 15:31:28

US3522112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Dec 2020 22:19:17

US3522112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '9 Dec 2020'	(b) (4) Yaman Ahmed (b) (4)	09 Dec 2020 22:19:17

US3522112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	09 Dec 2020 22:19:17

US3522112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	Yaman Ahmed (b) (4)	09 Dec 2020 22:19:17

US3522112

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Dec 2020 22:19:23

US3522112

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered 'I'	System	09 Dec 2020 22:19:23

US3522112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:55:38

US3522112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:55:38

US3522112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:55:38

US3522112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4), (b) (6)	08 Jan 2021 20:55:38

US3522112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:55:43

US3522112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered 'I'	System	08 Jan 2021 20:55:43

US3522112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	06 Feb 2021 15:43:15

US3522112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '6 Feb 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	06 Feb 2021 15:43:15

US3522112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:43:15

US3522112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:43:15

US3522112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:43:19

US3522112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered 'I'	System	06 Feb 2021 15:43:19

US3522112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:18:59

US3522112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:18:59

US3522112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:18:59

US3522112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered 'VISIT4'	System	10 Mar 2021 15:18:59

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered empty.	System	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered empty.	System	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered empty.	System	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered empty.	System	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered empty.	System	30 Mar 2021 19:28:39

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17

US3522112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17

US3522112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:06

US3522112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:06

US3522112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:37

US3522112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:37

US3522112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered '10:15'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:37

US3522112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered '10 Mar 2021 10:15'	System	10 Mar 2021 15:19:37

US3522112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:19:42

US3522112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:17
User entered 'I'	System	10 Mar 2021 15:19:42

US3522112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 16:51:09

US3522112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered '8 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 16:51:09

US3522112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 16:51:09

US3522112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 16:51:09

US3522112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 16:51:14

US3522112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:06
User entered 'I'	System	08 Apr 2021 16:51:14

US3522112

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:02:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:20:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:05
User entered 'Yes (Y)'	(b) (4) Jelena Verkler (b) (4)	16 Mar 2021 15:00:35

US3522112

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:05

US3522112

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Jan 2021'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:05

US3522112

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:05

US3522112

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 15:17:05

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Jan 2021'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:05
User entered '0'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 18:51:51
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:48:41

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 18:51:51
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:48:41

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Jan 2021'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 07:10:23
User entered 'mRNA-1273 (mRNA-1273)'	Alandra White (b) (4)	13 Jan 2021 15:17:44
	(b) (4)	

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 07:10:23
User entered 'mRNA-1273 (mRNA-1273)'	Alandra White (b) (4) (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Jan 2021 15:17:44

US3522112

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered empty.	System	13 Jan 2021 15:17:44

US3522112

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:34:44

US3522112

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Jan 2021 15:46:19
User entered '13 Jan 2021' reason for change: Data Entry Error	System	13 Jan 2021 15:46:19
User opened query 'Data is required. Please provide.' (Site from System).	Alandra White (b) (4)	13 Jan 2021 15:34:44
User entered empty.	(b) (4)	13 Jan 2021 15:34:44

US3522112

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '10:28'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:34:44

US3522112

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '13 Jan 2021 10:28'	System	13 Jan 2021 15:46:19
User entered empty.	System	13 Jan 2021 15:34:44

US3522112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:34:52

US3522112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '13 Jan 2021'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:34:52

US3522112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '10:30'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:34:52

US3522112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:41:46
User entered '13 Jan 2021 10:30'	System	13 Jan 2021 15:34:52

US3522112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:02:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:30:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:30:19
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:05
User entered 'No (N)'	(b) (4) Jelena Verkler (b) (4) (b) (4)	16 Mar 2021 15:00:18

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:11:16
User entered		
'USA-US131-2021-mRNA-1273-P301000016'	System	20 Apr 2021 17:11:08
User entered 'New'	(b) (4), (b) (6)	20 Apr 2021 17:11:08

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The event term 'asthma exacerbation with new congestive heart failure diagnosis-moderate' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:35:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea exertional, LLT: Exertional dyspnea - version MedDRA\\23.0.	Coder Import (b) (4)	03 May 2021 17:49:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 May 2021 17:49:33
Data point term sent to Coder	System	03 May 2021 17:48:30
Query 'PV Query: The event term 'asthma exacerbation with new congestive heart failure diagnosis-moderate' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated term ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 17:48:03
Coding entries removed.	(b) (4)	
	Alandra White (b) (4)	03 May 2021 17:47:49
Signature has been broken.	(b) (4)	
	Alandra White (b) (4)	03 May 2021 17:47:49
User entered 'Exertional dyspnea' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: The event term 'asthma exacerbation with new congestive heart failure diagnosis-moderate' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	Alandra White (b) (4)	03 May 2021 17:47:49
	(b) (4), (b) (6)	29 Apr 2021 13:11:12
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 11:26:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	21 Apr 2021 11:26:55
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
Data point term sent to Coder	(b) (4)	
User entered 'ATHSMA EXACERBATION WITH new Congestive Heart Failure DIAGNOSIS-MODERATE' reason for change: Data Entry Error	System	19 Apr 2021 18:34:26
Data point term sent to Coder	(b) (4), (b) (6)	19 Apr 2021 18:33:32
	System	19 Apr 2021 18:32:23

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Athsma exacerbation with CHF new diagnosis- moderate'	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:32:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:32:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:32:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:31:54
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	Alandra White (b) (4)	03 May 2021 17:39:37
	(b) (4)	
User entered '19 Apr 2021' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 17:39:37
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
	(b) (4)	
User entered '14 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
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).	(b) (4) System	19 Apr 2021 18:32:36
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	19 Apr 2021 18:31:54
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 18:32:36
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Apr 2021 18:32:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:32:36
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	19 Apr 2021 18:31:54
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating event end date to date subject returned to baseline (per SD, 19 Apr 2021)' (Site from Safety). Signature has been broken.	(b) (4), (b) (6) Alandra White (b) (4)	03 May 2021 18:36:46 03 May 2021 17:47:49
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	03 May 2021 17:47:49
Query 'PV Query: Please consider updating event end date to date subject returned to baseline (per SD, 19 Apr 2021)' answered with 'updated as requested' (Site from Safety).	Alandra White (b) (4) (b) (4)	03 May 2021 17:39:59
User opened query 'PV Query: Please consider updating event end date to date subject returned to baseline (per SD, 19 Apr 2021)' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Marcus Zervos (b) (4)	29 Apr 2021 13:11:40 19 Apr 2021 19:00:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Signature has been broken.	Alandra White (b) (4)	03 May 2021 17:47:49
	(b) (4)	
User entered 'New diagnosis of congestive heart Failure' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 17:47:49
User signature succeeded.	(b) (4)	
	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject had a history of congestive heart failure prior to the onset of the event.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:37:19
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:37:00
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:36:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:35:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'updated per EHR ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 18:12:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated per EHR ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 18:11:47
Query 'PV Query: Please confirm if the subject had a history of congestive heart failure prior to the onset of the event.' answered with 'new diagnosis ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 18:11:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT ADMITTED FOR SOB. FOUND NEW DIAGNOSIS OF CHF. LABS ON 13-APR-2021 SHOWED AN ELEVATED D-DIMER OF 486NG/ML (REF <255NG/ML) AND BNP 604 PG/ML (REF <100PG/ML) COVID TESTING WAS NEGATIVE.13-APR-2021 CHEST XRAY RESULTS: IMPRESSION: THERE IS MILD CARDIOMEGALY WITHOUT EVIDENCE OF ACUTE PULMONARY PROCESS. Patient was given 324 mg of aspirin and 250 mg bolus of normal saline in the ED. once admitted on the floor patient was given IV Lasix 20 mg ECHOCARDIOGRAM 14-APR-2021 SHOWED LVEF 15-20% AND PARTICIPANT WAS REFERRED FOR CARDIAC CATHETERIZATION. PARTICIPANT MEDS CHANGED BUT DOES NOT KNOW THEM AT THIS TIME. WAITING FOR DC INFO. RETURNED TO NEW BASELINE AS OF 4/19/21' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 18:11:19
User entered 'PATIENT ADMITTED FOR SOB. FOUND NEW DIAGNOSIS OF CHF. LABS ON 13-APR-2021 SHOWED AN ELEVATED D-DIMER OF 486NG/ML (REF <255NG/ML) AND BNP 604 PG/ML (REF <100PG/ML) COVID TESTING WAS NEGATIVE.13-APR-2021 CHEST XRAY RESULTS: IMPRESSION: THERE IS MILD CARDIOMEGALY WITHOUT EVIDENCE OF ACUTE PULMONARY PROCESS. Echocardiogram 14-Apr-2021 showed LVEF 15-20% and participant was referred for cardiac catheterization. PARTICIPANT MEDS CHANGED BUT DOES NOT KNOW THEM AT THIS TIME. WAITING FOR DC INFO. RETURNED TO NEW BASELINE AS OF 4/19/21' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 18:09:16
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'result was negative ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 18:01:17
Signature has been broken.	Alandra White (b) (4)	03 May 2021 18:00:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT ADMITTED FOR SOB. FOUND NEW DIAGNOSIS OF CHF. Labs on 13-Apr-2021 showed an elevated D-dimer of 486ng/mL (ref <255ng/mL) and BNP 604 pg/mL (ref <100pg/mL) Covid testing was negative.13-Apr-2021 Chest Xray results: IMPRESSION: There is mild cardiomegaly without evidence of acute pulmonary process. PARTICIPANT MEDS CHANGED BUT DOES NOT KNOW THEM AT THIS TIME. WAITING FOR DC INFO. RETURNED TO NEW BASELINE AS OF 4/19/21' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 18:00:55
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:10:41
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:10:03
User opened query 'PV Query: Please confirm if the subject had a history of congestive heart failure prior to the onset of the event.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:08:58
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:08:10

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:07:59
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:07:46
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:14
User entered 'PATIENT ADMITTED FOR SOB. FOUND NEW DIAGNOSIS OF CHF. PARTICIPANT MEDS CHANGED BUT DOES NOT KNOW THEM AT THIS TIME. WAITING FOR DC INFO. Returned to new baseline as of 4/19/21' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:32:56
User entered 'Patient admitted for SOB. Found new diagnosis of CHF. Participant meds changed but does not know them at this time. Waiting for DC info.'	(b) (4), (b) (6)	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 18:31:54

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 20:49:31
User entered 'USA-US131-2021-mRNA-1273-P301000016'	(b) (4), (b) (6)	03 May 2021 20:48:53

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 19:24:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 19:24:29
Data point term sent to Coder	System	03 May 2021 18:52:41
User entered 'New Diagnosis of Congestive heart Failure'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	03 May 2021 19:08:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

None

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant received new diagnosis as a result of ED visit for exertional dyspnea. 15-Apr-2021 she was started on valsartan 40mg, once daily and was tolerating well as of 19-Apr-2021. On 20-Apr-2021 she had a Coronary angiogram and left ventricular gram/pressure which showed normal coronary arteries with an EF of 25-30% with a markedly dilated left ventricle consistent with a nonischemic cardiomyopathy. LVEDP was 17 mm Hg. Current plan is to repeat an echocardiogram in 3 months to assess need for an AICD.'	Alandra White (b) (4)	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:52:04

US3522112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:52:04

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 14:13:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 14:13:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	13 Aug 2020 14:13:49
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 14:13:45
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:13:45

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 14:17:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:17:20
Data point term sent to Coder	System	13 Aug 2020 14:16:14
User entered 'Synthroid'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Hypothyroidism'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR RQ: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 07:29:37
User entered '88' reason for change: New Information	Sharon Mathys (b) (4)	29 Oct 2020 14:41:13
Query 'Per DM CLR RQ: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	29 Oct 2020 14:40:26
User entered '75' reason for change: New Information	Sharon Mathys (b) (4)	29 Oct 2020 14:40:13
User opened query 'Per DM CLR RQ: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:44:56
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:17:51
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'yes' (Site from DM).	Kristin Eis (b) (4)	24 Sep 2020 16:51:53
User entered '80' reason for change: Data Entry Error	Kristin Eis (b) (4)	24 Sep 2020 16:51:48
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:15:23

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.80'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Kristin Eis (b) (4)	24 Sep 2020 16:51:48
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:15:58
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:15:58

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 11:41:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 11:41:23
Data point term sent to Coder	System	13 Aug 2020 14:22:25
User entered 'Janumet'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'NIDDM II'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not dash (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 05:51:05
Query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not dash (e.g. 5/325). If so please update eCRF as appropriate.' answered with 'yes ' (Site from DM).	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:52:23
User entered '50' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:52:19
User opened query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not dash (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:15:44
User entered '50-1,000'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'twice daily (BID)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:22:14
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:22:14

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 14:24:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:24:24
Data point term sent to Coder	System	13 Aug 2020 14:23:27
User entered 'Diclofenac'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (generalize or local (e.g. knees, hips etc.) . Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (generalize or local (e.g. knees, hips etc.) . Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'for all over body-shoulder, back, etc' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 05:52:31
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (generalize or local (e.g. knees, hips etc.) . Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:52:53
User entered 'Osteoarthritis'	(b) (4), (b) (6)	24 Sep 2020 05:16:02
	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '100'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:23:15
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:23:15

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User closed query 'Per DM CLR: Please review the components of this combination drug as this is not the standard components (e.g., 160/4.5 ug, 80/4.5 ug , etc.). Please update as applicable or provide explanation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 04:08:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 13:16:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 13:16:34
Data point term sent to Coder	System	02 Feb 2021 13:15:45
Query 'Per DM CLR: Please review the components of this combination drug as this is not the standard components (e.g., 160/4.5 ug, 80/4.5 ug , etc.). Please update as applicable or provide explanation ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:15:36
Coding entries removed.	(b) (4), (b) (6)	02 Feb 2021 13:15:30
User entered 'SYMBICORT' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 13:15:30
User opened query 'Per DM CLR: Please review the components of this combination drug as this is not the standard components (e.g., 160/4.5 ug, 80/4.5 ug , etc.). Please update as applicable or provide explanation ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:59:35

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:04:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:04:13
Data point term sent to Coder	System	13 Aug 2020 14:25:34
User entered 'Symbicort 160/45.5'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Asthma'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:57
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 160/4.5). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 04:53:15
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 160/4.5). Please correct the dosage or provide explanation for alternate dosage. ' answered with 'dose updated ' (Site from DM).	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:37:35
Signature has been broken.	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:37:16
User entered '160/4.5' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:37:16
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 160/4.5). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:04:55
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:40
User entered '160/45.5' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 13:15:30
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 13:15:30
User entered 'puff (PUFF)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'once daily (QD)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	13 Jan 2021 15:45:09
User entered 'Yes (Y)'	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	13 Jan 2021 15:45:09
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User entered '1'	System	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User entered '1'	System	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:20:09
User entered '804 (804)'	System	13 Aug 2020 14:24:36

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:17:08
Data point term sent to Coder	System	13 Aug 2020 14:27:45
User entered 'Aspirin'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'S/P Pulmonary Emboli'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '81'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'I'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:27:12
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:27:12

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:27:12

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:27:12

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ALPHA- AND BETA-ADRENORECEPTOR AGONISTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: EPIPEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 05:16:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 05:16:12
Data point term sent to Coder	System	13 Aug 2020 14:29:53
User entered 'EpiPen'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Asthma'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered '0.3'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'as needed (PRN)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:29:34
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 14:29:34

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 14:32:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:32:26
Data point term sent to Coder	System	13 Aug 2020 14:30:55
User entered 'Crestor'	Yaman Ahmed (b) (4) (b) (4)	13 Aug 2020 14:30:46

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Hypercholesteremia'	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '10'	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	13 Aug 2020 14:30:46
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:30:46

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:30:46

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:30:46

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 15:37:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:37:47
Data point term sent to Coder	System	03 Oct 2020 15:36:56
User entered 'Sertraline'	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'depression'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '50'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'mg (mg)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '1'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	03 Oct 2020 15:36:11
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:36:11

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE;VILANTEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Jan 2021 15:53:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:53:24
Data point term sent to Coder	System	13 Jan 2021 15:44:55
User entered 'fluticasone and vilanterol'	Alandra White (b) (4) (b) (4)	13 Jan 2021 15:44:18

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Asthma'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '100-25'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'ug (ug)'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'once daily (QD)'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '16 Dec 2020'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '0'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Yes (Y)'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered empty.	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'No (N)'	Alandra White (b) (4)	13 Jan 2021 15:44:18
	(b) (4)	

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:44:18

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:44:18

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:44:18

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:27:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:27:21
Data point term sent to Coder	System	03 May 2021 18:14:52
User entered 'aspirin'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'exertional dyspnea'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '324'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:13:54

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:18:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:18:22
Data point term sent to Coder	System	03 May 2021 18:15:53
User entered 'normal saline (NaCl 0.9%)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Exertional dyspnea'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:15:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:18:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:18:22
Data point term sent to Coder	System	03 May 2021 18:16:57
User entered 'Furosemide (lasix)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'exertional dyspnea'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:16:32

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:22:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:22:38
Data point term sent to Coder	System	03 May 2021 18:18:58
User entered 'predniSONE'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'exertional dyspnea'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

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

Audit	User	Time (GMT)
User entered '15 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 18:18:03

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[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: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:43:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:43:22
Data point term sent to Coder	System	03 May 2021 18:33:11
User entered 'valsartan'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'new diagnosis of heart failure'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:32:44

US3522112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 18:32:44

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:02:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	13 Jan 2021 15:36:41

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Alandra White (b) (4)	13 Jan 2021 15:37:37
	(b) (4)	
User entered '13 Jan 2021'	Alandra White (b) (4)	13 Jan 2021 15:37:14
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Steroid injection bilateral shoulders'	Alandra White (b) (4)	13 Jan 2021 15:37:14
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:40
	(b) (4)	
User entered 'Medical History (MH)'	Alandra White (b) (4)	13 Jan 2021 15:37:14
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:40
User entered empty.	Alandra White (b) (4) (b) (4)	13 Jan 2021 15:37:14

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered '13 Apr 2021'	Alandra White (b) (4)	03 May 2021 17:51:06
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Blood draw for D-dimer, BNP'	Alandra White (b) (4)	03 May 2021 17:51:06
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Adverse Event (AE)'	Alandra White (b) (4)	03 May 2021 17:51:06
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	03 May 2021 18:06:47
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 17:51:06

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered '13 Apr 2021'	Alandra White (b) (4)	03 May 2021 17:56:13
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Chest X-ray'	Alandra White (b) (4)	03 May 2021 17:56:13
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Adverse Event (AE)'	Alandra White (b) (4)	03 May 2021 17:56:13
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	03 May 2021 18:06:47
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 17:56:13

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered '13 Apr 2021'	Alandra White (b) (4)	03 May 2021 18:00:19
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Covid-19 Testing'	Alandra White (b) (4)	03 May 2021 18:00:19
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Adverse Event (AE)'	Alandra White (b) (4)	03 May 2021 18:00:19
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	03 May 2021 18:06:47
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:00:19

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered '14 Apr 2021'	Alandra White (b) (4)	03 May 2021 18:03:44
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
User entered 'Echocardiogram without contrast'	(b) (4) Alandra White (b) (4)	03 May 2021 18:03:44

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 18:06:47
	(b) (4)	
User entered 'Adverse Event (AE)'	Alandra White (b) (4)	03 May 2021 18:03:44
	(b) (4)	

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	03 May 2021 18:06:47
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 18:03:44

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Apr 2021'	Alandra White (b) (4) (b) (4)	03 May 2021 19:04:00

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CORONARY ANGIOGRAM AND LEFT VENTRICULAR GRAM/PRESSURE'	Alandra White (b) (4) (b) (4)	03 May 2021 19:04:00

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Alandra White (b) (4) (b) (4)	03 May 2021 19:04:00

US3522112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	03 May 2021 19:04:00

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'USA-US131-2021-MRNA-1273-P301000016'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	03 May 2021 20:48:53
Signature has been broken.	System	03 May 2021 20:48:53
User entered 'Yes (Y)'	System	03 May 2021 20:48:53
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Marcus'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Paul'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Zervos'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Kilgore'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '2799 West Grand Blvd'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Detroit'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered empty.	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'MI'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered (b) (6)'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered '48301'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered 'US'	(b) (4) System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 20:55:59
User entered '2'	System	03 May 2021 18:39:01
User entered '1'	System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'USA-US131-2021-MRNA-1273-P301000016'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	03 May 2021 20:48:53
Signature has been broken.	System	03 May 2021 20:48:53
User entered 'Yes (Y)'	System	03 May 2021 20:48:53
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Marcus'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Paul'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Zervos'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Kilgore'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '2799 West Grand Blvd'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Detroit'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered empty.	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'MI'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '48202'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered 'US'	(b) (4) System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 20:55:59
User entered '2'	System	03 May 2021 18:39:01
User entered '1'	System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered '20/Apr/2021 15:13'	(b) (4) System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'USA-US131-2021-MRNA-1273-P301000016'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	03 May 2021 20:48:53
Signature has been broken.	System	03 May 2021 20:48:53
User entered 'Yes (Y)'	System	03 May 2021 20:48:53
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Marcus'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Paul'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Zervos'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Kilgore'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '2799 West Grand Blvd'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Detroit'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered empty.	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'MI'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '48202'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered 'US'	(b) (4) System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 20:55:59
User entered '2'	System	03 May 2021 18:39:01
User entered '1'	System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 11:38'	System	03 May 2021 18:39:01

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User entered 'I'	(b) (4), (b) (6)	03 May 2021 18:39:01

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'USA-US131-2021-MRNA-1273-P301000016'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Yes (Y)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	03 May 2021 20:48:53
Signature has been broken.	System	03 May 2021 20:48:53
User entered 'Yes (Y)'	System	03 May 2021 20:48:53
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'No (N)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Marcus'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Paul'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Zervos'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'Kilgore'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '2799 West Grand Blvd'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered 'Detroit'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6) '	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered empty.	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered 'MI'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
Un-reviewed for Safety.	System	03 May 2021 18:39:01
Signature has been broken.	System	03 May 2021 18:39:01
User entered '48202'	System	03 May 2021 18:39:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:12:12
User entered (b) (6)'	System	20 Apr 2021 17:11:08

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:40:08
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:00:34
User entered 'US'	(b) (4) System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 20:55:59
User entered '2'	System	03 May 2021 18:39:01
User entered '1'	System	20 Apr 2021 19:13:21

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 13:55'	System	03 May 2021 20:55:59

US3522112

Folder: SAE USA-US131-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 May 2021 20:55:59