

US3522513 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:01:08

All time stamps listed in this document are displayed in GMT

US3522513

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:25:11

Generated On: 10 Jun 2021 08:01:08

Participant ID

US3522513

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

US3522513

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3522513

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
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	False
Black	True
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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	DIABETES MELLITUS TYPE 2
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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	HYPERLIPIDEMIA
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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	CERVICAL ARTHRITIS
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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	GENITAL HERPES
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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	01 MAY 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 MAY 2002
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2002
Start Year (derived)	2002
Stop Month and Year (derived)	MAY 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Condition	BENIGN RIGHT-SIDED THYROID NODULE
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)	

US3522513

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:01 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 08:01
Height (<i>xxx.x</i>)	66.3 in
Weight (<i>xxx.x</i>)	195.6 lb
BMI (<i>xxx.x</i>)	31.35102 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) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*) 2 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) 1 MAY 2002

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

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) 05 Mar 2021 17:25:12

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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 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145550

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

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 19:09:50

Generated On: 10 Jun 2021 08:01:08

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)	2 SEP 2020
Time of assessment (00:00-23:59)	08:01 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 08:01
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 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 19:09:50

Generated On: 10 Jun 2021 08:01:08

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)	2 SEP 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:10
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 19:09:50

Generated On: 10 Jun 2021 08:01:08

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 19:09:50

Generated On: 10 Jun 2021 08:01:08

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 09:40

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	08:18 (24 HR)
Collection date and time (derived)	2 SEP 2020 08:18

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:20	2 SEP 2020 08:20
Nasopharyngeal Swab 2	No		

US3522513

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 10:13

PC Open Date & Time

02 SEP 2020 10:00

PC Close Date & Time

02 SEP 2020 12:30

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 97.1 °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	02 SEP 2020 13:50
PC Open Date & Time	02 SEP 2020 13:25
PC Close Date & Time	03 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

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

03 SEP 2020 12:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

96.4 °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

04 SEP 2020 17:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.6 °F

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

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

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

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

PC Time Stamp 05 SEP 2020 21:58

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

02 SEP 2020 10:14

PC Open Date & Time

02 SEP 2020 10:00

PC Close Date & Time

02 SEP 2020 12:30

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

02 SEP 2020 13:50

PC Open Date & Time

02 SEP 2020 13:25

PC Close Date & Time

03 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

03 SEP 2020 12:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

04 SEP 2020 17:54

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

05 SEP 2020 21:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

06 SEP 2020 12:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

07 SEP 2020 12:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:14
PC Open Date & Time	02 SEP 2020 10:00
PC Close Date & Time	02 SEP 2020 12:30

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 13:51
PC Open Date & Time	02 SEP 2020 13:25
PC Close Date & Time	03 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 ☒

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EAB) (1725)

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US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

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)

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 ☒

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:58
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

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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US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:16
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

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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US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3522513

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 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

US3522513

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:18:33

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 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

US3522513

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:33 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:33
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:09
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3522513

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 09:39 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 09:39

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3522513

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

28 SEP 2020 08:40

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:45	28 SEP 2020 08:45
Nasopharyngeal Swab 2	No		

US3522513

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 10:08

PC Open Date & Time

28 SEP 2020 09:59

PC Close Date & Time

28 SEP 2020 12:29

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 97.9 °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	28 SEP 2020 13:33
PC Open Date & Time	28 SEP 2020 13:24
PC Close Date & Time	29 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

98.1 °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

29 SEP 2020 12:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:23

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

97.9 °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 03 OCT 2020 12:01

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

96.9 °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

04 OCT 2020 12:48

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

28 SEP 2020 10:06

PC Open Date & Time

28 SEP 2020 09:59

PC Close Date & Time

28 SEP 2020 12:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

28 SEP 2020 13:30

PC Open Date & Time

28 SEP 2020 13:24

PC Close Date & Time

29 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

29 SEP 2020 12:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

30 SEP 2020 12:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

01 OCT 2020 12:23

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

03 OCT 2020 12:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

04 OCT 2020 12:48

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 10:06
PC Open Date & Time	28 SEP 2020 09:59
PC Close Date & Time	28 SEP 2020 12:29

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:33
PC Open Date & Time	28 SEP 2020 13:24
PC Close Date & Time	29 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

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
EAB) (1725)

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US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 ☒

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1923

EAB) (1725)

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 12:24
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 ☒

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:02
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 ☒

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 ☒

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:49
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3522513

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments PATIENT HAD PAIN/ SORENESS
AROUND THE INJECTION SITE
THE DAY AFTER THE
INJECTION 9/29, TOOK TWO
400MG TYLENOLS TABLETS.
PATIENTS SORENESS WENT
AWAY THE NEXT DAY.

If Contact Not Made, please provide Comments

US3522513

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments SEE SOURCE. 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

US3522513

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 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."

US3522513

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:48

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	07:20 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 07:20
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522513

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3522513

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

07:30 (24 HR)

Collection date and time (derived)

26 OCT 2020 07:30

US3522513

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:09:50

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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	02 NOV 2020 07:59:15
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

09 NOV 2020 00:06:16

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

17 NOV 2020 09:09:25

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 14:01:36
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 09:30:02
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 03:42:59
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	11 DEC 2020 21:51:24
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 10:54:26

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

25 DEC 2020 01:30:44

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 08:12:12
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 JAN 2021 19:01:23
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

18 JAN 2021 17:59:22

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

24 JAN 2021 18:27:46

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:43:30

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 FEB 2021 15:38:27
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:03:18
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

21 FEB 2021 10:31:05

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

28 FEB 2021 17:10:21

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

07 MAR 2021 10:11:59

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 13:09:40
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

21 MAR 2021 12:00:54

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

28 MAR 2021 12:02:19

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

02 APR 2021 00:02:23

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

09 APR 2021 02:10:32

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

16 APR 2021 12:29:14

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

23 APR 2021 12:23:49

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

02 MAY 2021 10:04:09

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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°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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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="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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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 <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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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"/>

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3522513

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:01:08

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		28 FEB 2021 17:10:31

US3522513

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

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

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

US3522513

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 DEC 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

US3522513

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 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

US3522513

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

R KNEE INJURY ON 24 DEC 2020;
GIVEN CRUTCHES, KNEE
BRACE AND NORCO 10/325 FOR
A WEEK. THEN F/U IN 05 FEB
2021, WAS GIVEN SAME NORCO
FOR A WEEK AND TOLD THAT
SHE NEEDS TOTAL KNEE
REPLACEMENT (24 MARCH)

US3522513

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:23:19

Generated On: 10 Jun 2021 08:01:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:48:24

Generated On: 10 Jun 2021 08:01:08

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) _____

US3522513

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:23:19

Generated On: 10 Jun 2021 08:01:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3522513

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:23:19

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

22 MAR 2021 13:30

US3522513

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:23:19

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 20:47:44

Generated On: 10 Jun 2021 08:01:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A VOICEMAIL MESSAGE

If Contact Not Made, please provide Comments

US3522513

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 20:47:44

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522513

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522513

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:08

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

US3522513

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:01:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522513

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:25:12

Generated On: 10 Jun 2021 08:01:08

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

Visit date (dd MMM yyyy)	28 JAN 2021
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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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US3522513

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:24:41

Generated On: 10 Jun 2021 08:01:08

Date of updated informed consent (*dd MMM yyyy*) 28 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*) 28 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 _____

US3522513

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:25:11

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

12:01 (24 HR)

Collection date and time (derived)

28 JAN 2021 12:01

US3522513

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:25:11

Generated On: 10 Jun 2021 08:01:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	12:00
Collection Date and Time (derived)	28 JAN 2021 12:00

US3522513

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 15:39:52

Generated On: 10 Jun 2021 08:01:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:01:08

AEID	USA-US131-2021-MRNA-1273-P30 1000017
Adverse event	RIGHT KNEE INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 DEC 2020
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 type="radio"/> Grade 3/Severe <input checked="" 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)	24 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	24 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:01:08

Number of Days in ICU	
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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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	

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:01:08

RIGHT KNEE INJURY ON 11 DEC
2020, WITH ORTHOPEDIC
FOLLOW UP ON 24 DEC 2020;
WAS GIVEN CRUTCHES, KNEE
BRACE AND NORCO 10/325 FOR
A WEEK THEN WENT BACK IN
05 FEB 2021 FOR A FOLLOW UP
AND WAS GIVEN SAME NORCO
FOR A WEEK AND WAS TOLD
THAT SHE NEEDS TOTAL RIGHT
KNEE REPLACEMENT
(ARTHROPLASTY) SURGERY (24
MARCH 2021)...
30 APR 2021 UPDATE: SURGERY
HAS NOT RECOVERED WELL,
SO SHE'S DUE BACK ON 03 MAY
2021 FOR A REPEAT SURGERY
(MANIPULATION UNDER
ANESTHESIA PER PCP NOTE ON
26 APR 2021 IN EMR). SHE IS
STILL TAKING OXYCODONE
AND ROBAXIN AS NEEDED TO
MANAGE PAIN SINCE
SURGERY.

REVIEWED AND GRADED BY
DR. KILGORE.

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)	

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:25:11

Generated On: 10 Jun 2021 08:01:08

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

Yes ☒

No ☐

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

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication CERVICAL ARTHRITIS

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	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) _____		
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	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) _____		
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 (3)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication GENITAL HERPES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	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) _____		
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"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 650

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE INJURY

Dose per administration 10/325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	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)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE INJURY

Dose per administration 10/325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 FEB 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"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF BLOOD CLOTS
POST-RIGHT TOTAL KNEE
REPLACEMENT

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 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"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN POST- RIGHT TOTAL KNEE
REPLACEMENT

Dose per administration 975

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 MAR 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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN POST RIGHT TOTAL KNEE
REPLACEMENT

Dose per administration 5-10

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

If dose unit is Other, specify

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

If frequency is Other, specify

AS NEEDED EVERY 6 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 MAR 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)		_____
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 (10)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication PAIN POST RIGHT TOTAL KNEE
REPLACEMENT

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PAIN POST TOTAL RIGHT KNEE
REPLACEMENT

Dose per administration 300

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

PRESCRIBED AS 300 MG THREE
TIMES A DAY BUT PATIENT
TAKES IT ONCE NIGHTLY
INSTEAD.

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 15:49:27

Generated On: 10 Jun 2021 08:01:08

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 17:25:11

Generated On: 10 Jun 2021 08:01:08

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 22:45:38

Generated On: 10 Jun 2021 08:01:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 NOV 2020	RIGHT-SIDED THYROID NODULE FNA BIOPSY	Medical History	
5 JAN 2021	RIGHT-SIDED THYROID NODULE FNA BIOPSY	Medical History	
24 DEC 2020	RIGHT KNEE BRACE	Adverse Event	
24 MAR 2021	ARTHROPLASTY ROBOT-ASSISTED RIGHT TOTAL KNEE	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:01:08

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:01:08

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 ☐

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 01:03:19

Generated On: 10 Jun 2021 08:01:08

SAEID	USA-US131-2021-MRNA-1273-P301000017
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)	2

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Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 01:03:19

Generated On: 10 Jun 2021 08:01:08

SAEID	USA-US131-2021-MRNA-1273-P301000017
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)	2
Date of submission (Pre-filled from custom function)	29/APR/2021 15:37
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

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 01:03:19

Generated On: 10 Jun 2021 08:01:08

SAEID	USA-US131-2021-MRNA-1273-P301000017
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)	2
Date of submission (Pre-filled from custom function)	30/APR/2021 12:45
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

US3522513 (Prod: Henry Ford Health System)

US3522513

Form: Participant Creation

Generated On: 10 Jun 2021 08:01:08

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 23:45:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
	(b) (4)	
User entered 'US3522513'	RWS_ENDPOINT	02 Sep 2020 11:49:57
	ENDPOINT (b) (4)	
	(b) (4)	

US3522513

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 11:52:36

US3522513

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:44
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:49:58

US3522513

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 11:52:36

US3522513

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'SCRN'	System	02 Sep 2020 11:52:36

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:49:59

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '46'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'YEARS'	System	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered '46'	System	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered 'Female (F)'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:32:48
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 11:58:33

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'Sep 2020'	System	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered '2020'	System	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 11:59:53

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:49:58

US3522513

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'I'	System	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:01:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:34:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:00:18

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:53:16
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'none' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:05:40
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:27:57
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:15:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:15:42
Data point term sent to Coder	System	02 Sep 2020 12:13:46
User entered 'Diabetes Mellitus Type 2'	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Sep 2020 12:44:59
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Sep 2020 12:13:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:44:59
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:13:41

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:16:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:16:42
Data point term sent to Coder	System	02 Sep 2020 12:14:47
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:14:36

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Arthritis of neck - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:11:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:11:40
Data point term sent to Coder	System	10 Nov 2020 21:10:20
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 21:09:51
User entered 'cervical ARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:09:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:25:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:25:52
Data point term sent to Coder	System	02 Sep 2020 12:24:56
User entered 'Arthritis'	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:24:53

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:26:42
Data point term sent to Coder	System	02 Sep 2020 12:25:58
User entered 'Genital Herpes'	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	02 Sep 2020 12:25:05

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:50:47
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:17:36
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 'unknown at this time' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:10:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 15:08:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Oct 2020 15:08:18
Data point term sent to Coder	System	06 Oct 2020 15:07:30
User entered 'HYSTERECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:06:49
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)	01 Oct 2020 08:28:23
Data point term sent to Coder	System	15 Sep 2020 13:39:56
User entered 'Sugically Sterile (Hysterectomy)'	Sharon Mathys (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '01 May 2002'	Sharon Mathys (b) (4) (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0'	Sharon Mathys (b) (4) (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:39:54
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' answered with 'fixed' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:10:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:06:49
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:28:40
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '01 May 2002' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:06:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:47
User entered '0'	Sharon Mathys (b) (4) (b) (4)	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'May 2002'	System	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered '2002'	System	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'May 2002'	System	06 Oct 2020 15:06:49
User entered empty.	System	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered '2002'	System	06 Oct 2020 15:06:49
User entered empty.	System	15 Sep 2020 13:39:20

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4)	27 Feb 2021 00:39:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Feb 2021 00:39:58
User closed query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify.	(b) (4), (b) (6)	25 Feb 2021 06:37:53
' (Site from DM).		
Query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify.	Alayna Wilder (b) (4)	23 Feb 2021 23:23:06
' answered with 'not applicable' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify.	(b) (4), (b) (6)	23 Feb 2021 10:17:59
' (Site from DM).		
User closed query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	23 Feb 2021 10:17:59
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Alayna Wilder (b) (4)	19 Feb 2021 18:56:45
' answered with 'updated' (Site from DM).	(b) (4)	

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Feb 2021 18:56:38
Coding entries removed.	Alayna Wilder (b) (4)	19 Feb 2021 18:56:20
	(b) (4)	
User entered 'benign RIGHT-SIDED THYROID NODULE' reason for change: Data Entry Error	Alayna Wilder (b) (4)	19 Feb 2021 18:56:20
	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	18 Feb 2021 15:47:46
' (Site from DM).		
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 14:08:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 14:08:35
	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 14:50:24
User entered 'Right-sided thyroid nodule'	Yaman Ahmed (b) (4)	26 Jan 2021 14:50:08
	(b) (4)	

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'l'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:36:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered empty.	System	26 Jan 2021 14:50:08

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	10 Sep 2020 13:35:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:35:05
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	10 Sep 2020 13:33:07
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	02 Sep 2020 18:48:38
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	02 Sep 2020 18:48:18
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:40
User entered '2 Sep 2020' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:35:40
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:35:40
User entered '08:01' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:35:40
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 08:01'	System	10 Sep 2020 13:35:40
User entered empty.	System	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Per CDM: Kindly complete the mandatory data fields for this form. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 05:22:08
Query 'Per CDM: Kindly complete the mandatory data fields for this form. ' answered with 'mandatory forms have been completed' (Site from DM).	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:22
User entered '66.3' in reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:33:07
User opened query 'Per CDM: Kindly complete the mandatory data fields for this form. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:34:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:48:38
User entered '66.3' in reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:48:18
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17
DataPoint set to visible.	System	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User entered '195.6' lb reason for change: Data Entry Error	Jelena Verkler (b) (4)	10 Sep 2020 13:34:49
User entered empty; reason for change Data Entry Error	(b) (4)	02 Sep 2020 18:48:38
User entered '195.6' lb reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:48:18
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17
DataPoint set to visible.	System	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '31.35102'	System	10 Sep 2020 13:34:49
User entered empty.	System	02 Sep 2020 18:48:38
User entered '31.35102'	System	02 Sep 2020 18:48:18
User entered empty.	System	02 Sep 2020 12:25:17
DataPoint set to visible.	System	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'kg/m2'	System	10 Sep 2020 13:34:49
User entered empty.	System	02 Sep 2020 18:48:38
User entered 'kg/m2'	System	02 Sep 2020 18:48:18
User entered empty.	System	02 Sep 2020 12:25:17
DataPoint set to visible.	System	02 Sep 2020 11:59:59

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:36:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:36:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:36:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:36:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'bpm'	System	10 Sep 2020 13:36:08
User entered empty.	System	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:36:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:36:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'breaths/min'	System	10 Sep 2020 13:36:08
User entered empty.	System	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:36:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:36:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	10 Sep 2020 13:36:08
User entered empty.	System	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:50:58
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:36:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 13:36:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	10 Sep 2020 13:36:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:35:05
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	10 Sep 2020 13:36:08
User entered empty.	System	02 Sep 2020 12:25:17

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22

US3522513

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22

US3522513

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	09 Dec 2020 01:51:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:31:12
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:26:21

US3522513

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:02
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Sep 2020 12:31:26
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:31:26
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Sep 2020 12:31:12
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:26:21

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	02 Sep 2020 12:27:10
User entered '1 May 2002' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:27:10
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	02 Sep 2020 12:26:48
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:26:48

US3522513

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:08

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:08
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:26:48

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Folder: Screening

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[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

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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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

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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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

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[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Form: Risk of Exposure

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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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:49:39
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:49:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:49:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:49:03
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:27:47
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:27:47

US3522513

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User closed query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	02 Sep 2020 12:56:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:56:29
User opened query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	02 Sep 2020 12:50:25
User entered 'works full remotely at home.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:50:25
User closed query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	02 Sep 2020 12:49:39
User opened query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	02 Sep 2020 12:49:03
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	02 Sep 2020 12:56:29
User entered '0' reason for change: Data Entry Error	System	02 Sep 2020 12:56:29
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 12:56:29
User entered '1' reason for change: Data Entry Error	System	02 Sep 2020 12:49:39
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 12:49:39
User entered '0' reason for change: Data Entry Error	System	02 Sep 2020 12:28:28
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 12:28:28
User entered '1'	System	02 Sep 2020 12:27:47
	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

US3522513

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 12:27:47

US3522513

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:27:47

US3522513

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:20
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:27:47

US3522513

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:28:49

US3522513

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:27
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:28:49

US3522513

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[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 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 12:28:49

US3522513

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'VISIT1'	System	02 Sep 2020 12:28:49

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:50:08

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered '145550'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:50:08

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 11:50:08

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:29:05

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:29:05

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:29:05

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:29:05

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:29:05

US3522513

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:51:30
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Sep 2020 19:37:42
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 04:49:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:49:20

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:54:04
User closed query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:58:35
Query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	29 Sep 2020 19:37:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 19:37:28
User opened query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:51:27
User entered '66.3' in	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:37:28
User entered '195.6' lb	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User closed query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:58:35
Query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:37:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:37:28
User opened query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:51:27
User entered '66.3' in	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:37:28
User entered '195.6' lb	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '08:01'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 08:01'	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 12:30:36
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:30:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 12:30:23
User entered '97.9' (non-conformant).	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'temporal'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '67'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'bpm'	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '16'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'breaths/min'	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '104'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 05:39:04
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jelena Verkler (b) (4) (b) (4)	17 Sep 2020 17:19:43
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:25:19
User entered '56'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:54:04
User closed query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:58:35
Query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	29 Sep 2020 19:37:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 19:37:28
User opened query 'Per CDM: If Screening and Day 1 were performed on the same day, Per CCGs pages 15 & 16 Height and Weight should be recorded as 'ND'. Please update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:51:27
User entered '66.3' in	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 19:37:28
User entered '195.6' lb	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:41:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:41:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:41:10
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:30:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '10:10' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 10:10'	System	02 Sep 2020 14:16:14
User entered empty.	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
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) (6)	18 Sep 2020 05:39:09
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).	Jelena Verkler (b) (4) (b) (4)	17 Sep 2020 17:20:09
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	17 Sep 2020 00:25:19
User entered '96.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '59' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'bpm'	System	02 Sep 2020 14:16:14
User entered empty.	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:04
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'breaths/min'	System	02 Sep 2020 14:16:14
User entered empty.	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4)	09 Dec 2020 01:54:04
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	02 Sep 2020 14:16:14
User entered empty.	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4)	09 Dec 2020 01:54:04
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 14:16:14
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'mmHg'	System	02 Sep 2020 14:16:14
User entered empty.	System	02 Sep 2020 12:30:23

US3522513

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:12
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:31:00

US3522513

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:12
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:31:00

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	02 Sep 2020 12:53:01
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 12:53:01
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	02 Sep 2020 12:34:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered '09:40' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 13:46:11
User entered '08:50' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:53:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 09:40'	System	02 Sep 2020 13:46:11
User entered '2 Sep 2020 08:50'	System	02 Sep 2020 12:53:01
User entered empty.	System	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:54:16
User entered 'ONCE'	System	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 12:34:05

US3522513

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:34:41

US3522513

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:20
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:34:41

US3522513

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:20
User entered '08:18'	(b) (4), (b) (6)	02 Sep 2020 12:34:41

US3522513

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 08:18'	System	02 Sep 2020 12:34:41

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:23
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:23
User entered '08:20'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered '2 Sep 2020 08:20'	System	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:23
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered empty.	System	02 Sep 2020 12:34:54

US3522513

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:35:03

US3522513

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:22
User entered 'I'	System	02 Sep 2020 12:35:03

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:13:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c5b2b18b-4c70-4676-8b76-dd811562c98f' User entered 'Yes (Y)'	System	02 Sep 2020 14:13:49
	System	02 Sep 2020 14:13:49

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:13:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c5b2b18b-4c70-4676-8b76-dd811562c98f' User entered '96.6'	System	02 Sep 2020 14:13:49
	System	02 Sep 2020 14:13:49

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:13:42', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c5b2b18b-4c70-4676-8b76-dd811562c98f' User entered 'No (N)'	System	02 Sep 2020 14:13:49
	System	02 Sep 2020 14:13:49

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:13:47', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c5b2b18b-4c70-4676-8b76-dd811562c98f' User entered '02 Sep 2020 10:13'	System	02 Sep 2020 14:13:49
	System	02 Sep 2020 14:13:49

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 10:00'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 09:10'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 12:30'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 11:40'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:49:41', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8f4bc77a-faf4-407c-917f-275a26a0bd6e' User entered 'Yes (Y)'	System	02 Sep 2020 17:50:03
	System	02 Sep 2020 17:50:03

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:49:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8f4bc77a-faf4-407c-917f-275a26a0bd6e' User entered '97.1'	System	02 Sep 2020 17:50:03
	System	02 Sep 2020 17:50:03

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:49:51', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8f4bc77a-faf4-407c-917f-275a26a0bd6e' User entered 'No (N)'	System	02 Sep 2020 17:50:03
	System	02 Sep 2020 17:50:03

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8f4bc77a-faf4-407c-917f-275a26a0bd6e' User entered '02 Sep 2020 13:50'	System	02 Sep 2020 17:50:03
	System	02 Sep 2020 17:50:03

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 13:25'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 12:35'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 2'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:04:55', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61704146-70db-489f-9042-91fe3a3fdd8f' User entered 'Yes (Y)'	System	03 Sep 2020 16:07:04
	System	03 Sep 2020 16:07:04

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61704146-70db-489f-9042-91fe3a3fdd8f' User entered '97.2'	System	03 Sep 2020 16:07:04
	System	03 Sep 2020 16:07:04

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61704146-70db-489f-9042-91fe3a3fdd8f' User entered 'No (N)'	System	03 Sep 2020 16:07:04
	System	03 Sep 2020 16:07:04

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61704146-70db-489f-9042-91fe3a3fdd8f' User entered '03 Sep 2020 12:05'	System	03 Sep 2020 16:07:04
	System	03 Sep 2020 16:07:04

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 3'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dde5c307-640c-4fc2-a2c2-973804e9c9b1' User entered 'Yes (Y)'	System	04 Sep 2020 21:53:55
	System	04 Sep 2020 21:53:55

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:41', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dde5c307-640c-4fc2-a2c2-973804e9c9b1' User entered '96.4'	System	04 Sep 2020 21:53:55
	System	04 Sep 2020 21:53:55

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:44', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dde5c307-640c-4fc2-a2c2-973804e9c9b1' User entered 'No (N)'	System	04 Sep 2020 21:53:55
	System	04 Sep 2020 21:53:55

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:51', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dde5c307-640c-4fc2-a2c2-973804e9c9b1' User entered '04 Sep 2020 17:53'	System	04 Sep 2020 21:53:55
	System	04 Sep 2020 21:53:55

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 4'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:57:43', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered 'Yes (Y)'	System	06 Sep 2020 01:58:24
	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:57:48', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered '96.6'	System	06 Sep 2020 01:58:24
	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7'	System	06 Sep 2020 01:58:24
User entered 'Yes (Y)'	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt took 650mg OTC Tylenol for pain at injection site ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:22:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered '1'	Alandra White (b) (4)	22 Oct 2020 19:38:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 01:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered '1'	System	06 Sep 2020 01:58:24
User entered '1'	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered '0'	System	06 Sep 2020 01:58:24
	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76ab9e49-0090-4eeb-b72b-e512b4797fc7' User entered '05 Sep 2020 21:58'	System	06 Sep 2020 01:58:24
	System	06 Sep 2020 01:58:24

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 5'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:15:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cfaa07e-e651-4e64-a35a-f4366e995da5' User entered 'Yes (Y)'	System	06 Sep 2020 16:16:09
	System	06 Sep 2020 16:16:09

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cfaa07e-e651-4e64-a35a-f4366e995da5' User entered '96.9'	System	06 Sep 2020 16:16:09
	System	06 Sep 2020 16:16:09

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:03', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cfaa07e-e651-4e64-a35a-f4366e995da5'	System	06 Sep 2020 16:16:09
User entered 'No (N)'	System	06 Sep 2020 16:16:09

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:07', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cfaa07e-e651-4e64-a35a-f4366e995da5' User entered '06 Sep 2020 12:16'	System	06 Sep 2020 16:16:09
	System	06 Sep 2020 16:16:09

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 6'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bd514949-2256-4d54-bfc4-2ac5d37dda10' User entered 'Yes (Y)'	System	07 Sep 2020 16:01:38
	System	07 Sep 2020 16:01:38

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:03', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bd514949-2256-4d54-bfc4-2ac5d37dda10' User entered '96.6'	System	07 Sep 2020 16:01:38
	System	07 Sep 2020 16:01:38

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bd514949-2256-4d54-bfc4-2ac5d37dda10' User entered 'No (N)'	System	07 Sep 2020 16:01:38
	System	07 Sep 2020 16:01:38

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bd514949-2256-4d54-bfc4-2ac5d37dda10' User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:01:38
	System	07 Sep 2020 16:01:38

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 7'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:30', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '94e415bb-962d-40ff-8ddd-d4538139bd2a' User entered 'Yes (Y)'	System	08 Sep 2020 16:02:32
	System	08 Sep 2020 16:02:32

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:34', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '94e415bb-962d-40ff-8ddd-d4538139bd2a' User entered '97.7'	System	08 Sep 2020 16:02:32
	System	08 Sep 2020 16:02:32

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '94e415bb-962d-40ff-8ddd-d4538139bd2a' User entered 'No (N)'	System	08 Sep 2020 16:02:32
	System	08 Sep 2020 16:02:32

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '94e415bb-962d-40ff-8ddd-d4538139bd2a' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 16:02:32
	System	08 Sep 2020 16:02:32

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:13:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61b7b3c2-95e0-4b84-97cb-5b3877e66a61' User entered 'None (1)'	System	02 Sep 2020 14:14:14
	System	02 Sep 2020 14:14:14

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61b7b3c2-95e0-4b84-97cb-5b3877e66a61' User entered 'No (N)'	System	02 Sep 2020 14:14:14
	System	02 Sep 2020 14:14:14

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:03', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61b7b3c2-95e0-4b84-97cb-5b3877e66a61' User entered 'No (N)'	System	02 Sep 2020 14:14:14
	System	02 Sep 2020 14:14:14

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61b7b3c2-95e0-4b84-97cb-5b3877e66a61' User entered 'None (1)'	System	02 Sep 2020 14:14:14
	System	02 Sep 2020 14:14:14

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '61b7b3c2-95e0-4b84-97cb-5b3877e66a61' User entered '02 Sep 2020 10:14'	System	02 Sep 2020 14:14:14
	System	02 Sep 2020 14:14:14

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 10:00'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 09:10'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 12:30'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 11:40'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8542f57c-e976-4d2c-8123-f23a27eb1e28'	System	02 Sep 2020 17:50:48
User entered 'None (1)'	System	02 Sep 2020 17:50:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8542f57c-e976-4d2c-8123-f23a27eb1e28' User entered 'No (N)'	System	02 Sep 2020 17:50:48
	System	02 Sep 2020 17:50:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:38', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8542f57c-e976-4d2c-8123-f23a27eb1e28' User entered 'No (N)'	System	02 Sep 2020 17:50:48
	System	02 Sep 2020 17:50:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:42', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8542f57c-e976-4d2c-8123-f23a27eb1e28'	System	02 Sep 2020 17:50:48
User entered 'None (1)'	System	02 Sep 2020 17:50:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:45', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8542f57c-e976-4d2c-8123-f23a27eb1e28' User entered '02 Sep 2020 13:50'	System	02 Sep 2020 17:50:48
	System	02 Sep 2020 17:50:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 13:25'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 12:35'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 2'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0b0e883-7d2c-48bc-8dd6-b941c6d78ac7'	System	03 Sep 2020 16:07:29
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:07:29

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0b0e883-7d2c-48bc-8dd6-b941c6d78ac7' User entered 'No (N)'	System	03 Sep 2020 16:07:29
	System	03 Sep 2020 16:07:29

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:50', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0b0e883-7d2c-48bc-8dd6-b941c6d78ac7' User entered 'No (N)'	System	03 Sep 2020 16:07:29
	System	03 Sep 2020 16:07:29

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0b0e883-7d2c-48bc-8dd6-b941c6d78ac7' User entered 'None (1)'	System	03 Sep 2020 16:07:29
	System	03 Sep 2020 16:07:29

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:05:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0b0e883-7d2c-48bc-8dd6-b941c6d78ac7'	System	03 Sep 2020 16:07:29
User entered '03 Sep 2020 12:05'	System	03 Sep 2020 16:07:29

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 3'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e5e3d4f9-4d68-4241-abab-8010feb252d1'	System	04 Sep 2020 21:54:10
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 21:54:10

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:53:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e5e3d4f9-4d68-4241-abab-8010feb252d1' User entered 'No (N)'	System	04 Sep 2020 21:54:10
	System	04 Sep 2020 21:54:10

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e5e3d4f9-4d68-4241-abab-8010feb252d1' User entered 'No (N)'	System	04 Sep 2020 21:54:10
	System	04 Sep 2020 21:54:10

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e5e3d4f9-4d68-4241-abab-8010feb252d1' User entered 'None (1)'	System	04 Sep 2020 21:54:10
	System	04 Sep 2020 21:54:10

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e5e3d4f9-4d68-4241-abab-8010feb252d1' User entered '04 Sep 2020 17:54'	System	04 Sep 2020 21:54:10
	System	04 Sep 2020 21:54:10

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 4'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:24', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2efdcad1-b380-4652-bf6a-8e8280fa1755'	System	06 Sep 2020 01:58:36
User entered 'None (1)'	System	06 Sep 2020 01:58:36

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2efdcad1-b380-4652-bf6a-8e8280fa1755'	System	06 Sep 2020 01:58:36
User entered 'No (N)'	System	06 Sep 2020 01:58:36

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2efdcad1-b380-4652-bf6a-8e8280fa1755'	System	06 Sep 2020 01:58:36
User entered 'No (N)'	System	06 Sep 2020 01:58:36

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2efdcad1-b380-4652-bf6a-8e8280fa1755'	System	06 Sep 2020 01:58:36
User entered 'None (1)'	System	06 Sep 2020 01:58:36

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:34', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2efdcad1-b380-4652-bf6a-8e8280fa1755'	System	06 Sep 2020 01:58:36
User entered '05 Sep 2020 21:58'	System	06 Sep 2020 01:58:36

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 5'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:10', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'cbd8497b-a76c-44af-ae83-bd81a1621240' User entered 'None (1)'	System	06 Sep 2020 16:16:21
	System	06 Sep 2020 16:16:21

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'cbd8497b-a76c-44af-ae83-bd81a1621240' User entered 'No (N)'	System	06 Sep 2020 16:16:21
	System	06 Sep 2020 16:16:21

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:14', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'cbd8497b-a76c-44af-ae83-bd81a1621240' User entered 'No (N)'	System	06 Sep 2020 16:16:21
	System	06 Sep 2020 16:16:21

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:17', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'cbd8497b-a76c-44af-ae83-bd81a1621240'	System	06 Sep 2020 16:16:21
User entered 'None (1)'	System	06 Sep 2020 16:16:21

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'cbd8497b-a76c-44af-ae83-bd81a1621240' User entered '06 Sep 2020 12:16'	System	06 Sep 2020 16:16:21
	System	06 Sep 2020 16:16:21

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 6'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '7015c7ce-56f0-464f-867d-aea8f9535f99'	System	07 Sep 2020 16:02:03
User entered 'None (1)'	System	07 Sep 2020 16:02:03

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '7015c7ce-56f0-464f-867d-aea8f9535f99'	System	07 Sep 2020 16:02:03
User entered 'No (N)'	System	07 Sep 2020 16:02:03

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:21', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '7015c7ce-56f0-464f-867d-aea8f9535f99'	System	07 Sep 2020 16:02:03
User entered 'No (N)'	System	07 Sep 2020 16:02:03

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:26', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '7015c7ce-56f0-464f-867d-aea8f9535f99'	System	07 Sep 2020 16:02:03
User entered 'None (1)'	System	07 Sep 2020 16:02:03

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:28', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '7015c7ce-56f0-464f-867d-aea8f9535f99' User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:02:03
	System	07 Sep 2020 16:02:03

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 7'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:42', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '48d8ada2-35e4-4309-a012-53296368565b'	System	08 Sep 2020 16:02:48
User entered 'None (1)'	System	08 Sep 2020 16:02:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:45', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '48d8ada2-35e4-4309-a012-53296368565b' User entered 'No (N)'	System	08 Sep 2020 16:02:48
	System	08 Sep 2020 16:02:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:47', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '48d8ada2-35e4-4309-a012-53296368565b' User entered 'No (N)'	System	08 Sep 2020 16:02:48
	System	08 Sep 2020 16:02:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:50', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '48d8ada2-35e4-4309-a012-53296368565b' User entered 'None (1)'	System	08 Sep 2020 16:02:48
	System	08 Sep 2020 16:02:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '48d8ada2-35e4-4309-a012-53296368565b' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 16:02:48
	System	08 Sep 2020 16:02:48

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:19', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered 'None (0)'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:44', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918'	System	02 Sep 2020 14:14:49
User entered 'No (N)'	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T10:14:47', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f5a61ca0-836d-4a12-a30a-5fd64f20a918' User entered '02 Sep 2020 10:14'	System	02 Sep 2020 14:14:49
	System	02 Sep 2020 14:14:49

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 10:00'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 09:10'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 12:30'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 11:40'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:50:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'None (0)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428'	System	02 Sep 2020 17:51:36
User entered 'Some interference with activity (2)'	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:14', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'None (0)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'None (0)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'None (0)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'None (0)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered 'No (N)'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-02T13:51:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '33365143-bb16-4b0f-b3d6-68a2a8890428' User entered '02 Sep 2020 13:51'	System	02 Sep 2020 17:51:36
	System	02 Sep 2020 17:51:36

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Sep 2020 13:25'	System	02 Sep 2020 13:46:11
User entered '02 Sep 2020 12:35'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 2'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02'	System	03 Sep 2020 16:07:51
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02'	System	03 Sep 2020 16:07:51
User entered 'Some interference with activity (2)'	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:24', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02' User entered 'None (0)'	System	03 Sep 2020 16:07:51
	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:26', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02' User entered 'None (0)'	System	03 Sep 2020 16:07:51
	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02' User entered 'None (0)'	System	03 Sep 2020 16:07:51
	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02' User entered 'None (0)'	System	03 Sep 2020 16:07:51
	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:34', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02'	System	03 Sep 2020 16:07:51
User entered 'No (N)'	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-03T12:06:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dbf18d7b-126b-4eed-a04e-3e4c577e4b02'	System	03 Sep 2020 16:07:51
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:51

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 3'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:15', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:30', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'None (0)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered 'No (N)'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-04T17:54:42', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '12db589c-3b8a-45bd-bdb9-9f658d8eb1f2' User entered '04 Sep 2020 17:54'	System	04 Sep 2020 21:54:44
	System	04 Sep 2020 21:54:44

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 4'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:42', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333'	System	06 Sep 2020 01:59:04
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'None (0)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:49', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'None (0)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:51', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'None (0)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:53', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'None (0)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:55', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'None (0)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered 'No (N)'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-05T21:58:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '77f33dd7-54e4-4781-ba67-eb2674676333' User entered '05 Sep 2020 21:58'	System	06 Sep 2020 01:59:04
	System	06 Sep 2020 01:59:04

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 5'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'None (0)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered 'No (N)'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-06T12:16:38', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51a078fb-c533-4865-9b76-aad755107631' User entered '06 Sep 2020 12:16'	System	06 Sep 2020 16:16:41
	System	06 Sep 2020 16:16:41

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 6'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'None (0)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:51', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered 'No (N)'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-07T12:01:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '682b0b23-ace9-40c4-9705-6e846a476fe3' User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:02:25
	System	07 Sep 2020 16:02:25

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 7'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:01:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:01', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'None (0)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered 'No (N)'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-08T12:02:14', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '515bd656-5b24-4a84-b7b9-b5870225e4d1' User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:11
	System	08 Sep 2020 16:03:11

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:53:01

US3522513

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:35
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	09 Sep 2020 13:22:26

US3522513

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:35
User entered '9 Sep 2020'	Alayna Wilder (b) (4) (b) (4)	09 Sep 2020 13:22:26

US3522513

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:35
User entered 'Contact Made (CONTACT MADE)'	Alayna Wilder (b) (4) (b) (4)	09 Sep 2020 13:22:26

US3522513

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:35
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.'"	Alayna Wilder (b) (4) (b) (4)	09 Sep 2020 13:22:26

US3522513

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:54:39
User entered 'Yes (Y)'		23 Sep 2020 13:07:58

US3522513

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'I'	System	23 Sep 2020 13:07:58

US3522513

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:40:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'No (N)'	(b) (4)	
	Sharon Mathys (b) (4)	09 Dec 2020 18:13:13
	(b) (4)	

US3522513

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:40:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Dec 2020 18:13:13

US3522513

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:40:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Dec 2020 18:13:13

US3522513

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:40:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Dec 2020 18:13:13

US3522513

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:41:05
User closed query 'Please enter details for Day 15 safety call as page cannot be left blank.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:41:03
Query 'Please enter details for Day 15 safety call as page cannot be left blank.' answered with 'updated. per source call was not attempted' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	09 Dec 2020 18:13:26
User opened query 'Please enter details for Day 15 safety call as page cannot be left blank.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 01:32:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 13:09:05

US3522513

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'I'	System	23 Sep 2020 13:09:05

US3522513

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 13:09:49

US3522513

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 13:09:49

US3522513

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 13:09:49

US3522513

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
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)	23 Sep 2020 13:09:49

US3522513

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:10
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 13:09:55

US3522513

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:16
User entered 'I'	System	23 Sep 2020 13:09:55

US3522513

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 12:36:59

US3522513

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 12:36:59

US3522513

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[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 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:25:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Sep 2020 12:36:59

US3522513

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'VISIT2'	System	28 Sep 2020 12:36:59

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '08:33'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '28 Sep 2020 08:33'	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '97.3' F	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Other (Other)'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'temporal'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '67'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'bpm'	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '15'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'breaths/min'	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '113'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '79'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
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	28 Sep 2020 14:11:06
User entered 'Yes (Y)' reason for change: Data Entry Error	System	28 Sep 2020 14:11:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43
		28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '10:09' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '28 Sep 2020 10:09'	System	28 Sep 2020 14:11:06
User entered empty.	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '59' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'bpm'	System	28 Sep 2020 14:11:06
User entered empty.	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'breaths/min'	System	28 Sep 2020 14:11:06
User entered empty.	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '126' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	28 Sep 2020 14:11:06
User entered empty.	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:11:06
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	28 Sep 2020 14:11:06
User entered empty.	System	28 Sep 2020 12:37:43

US3522513

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 12:37:51

US3522513

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 12:37:51

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '09:39'	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '28 Sep 2020 09:39'	System	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:26:58
User entered 'ONCE'	System	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 13:41:42

US3522513

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:03
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:21:00

US3522513

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:03
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:21:00

US3522513

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:03
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '08:40'	(b) (4), (b) (6)	28 Sep 2020 13:21:00

US3522513

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '28 Sep 2020 08:40'	System	28 Sep 2020 13:21:00

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '08:45'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '28 Sep 2020 08:45'	System	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered empty.	System	28 Sep 2020 13:21:38

US3522513

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:10
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:41:48

US3522513

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '1'	System	28 Sep 2020 13:41:48

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:08:24', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '583d3c52-0cf7-4f00-9b6e-232c6e1be05e' User entered 'Yes (Y)'	System	28 Sep 2020 14:08:42
	System	28 Sep 2020 14:08:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:08:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '583d3c52-0cf7-4f00-9b6e-232c6e1be05e' User entered '97.8'	System	28 Sep 2020 14:08:42
	System	28 Sep 2020 14:08:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:08:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '583d3c52-0cf7-4f00-9b6e-232c6e1be05e' User entered 'No (N)'	System	28 Sep 2020 14:08:42
	System	28 Sep 2020 14:08:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:08:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '583d3c52-0cf7-4f00-9b6e-232c6e1be05e' User entered '28 Sep 2020 10:08'	System	28 Sep 2020 14:08:42
	System	28 Sep 2020 14:08:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 09:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 12:29'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:32:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a8223a6f-b860-461b-9762-bfaded549377'	System	28 Sep 2020 17:33:14
User entered 'Yes (Y)'	System	28 Sep 2020 17:33:14

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:01', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a8223a6f-b860-461b-9762-bfaded549377' User entered '97.9'	System	28 Sep 2020 17:33:14
	System	28 Sep 2020 17:33:14

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a8223a6f-b860-461b-9762-bfaded549377'	System	28 Sep 2020 17:33:14
User entered 'No (N)'	System	28 Sep 2020 17:33:14

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a8223a6f-b860-461b-9762-bfaded549377' User entered '28 Sep 2020 13:33'	System	28 Sep 2020 17:33:14
	System	28 Sep 2020 17:33:14

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 2'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:19', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '5aa437d6-658d-4920-9dbe-30b0b73cdf8'	System	29 Sep 2020 16:00:47
User entered 'Yes (Y)'	System	29 Sep 2020 16:00:47

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:22', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '5aa437d6-658d-4920-9dbe-30b0b73cdf8'	System	29 Sep 2020 16:00:47
User entered '98.1'	System	29 Sep 2020 16:00:47

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '5aa437d6-658d-4920-9dbe-30b0b73cdf8'	System	29 Sep 2020 16:00:47
User entered 'No (N)'	System	29 Sep 2020 16:00:47

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '5aa437d6-658d-4920-9dbe-30b0b73cdf8'	System	29 Sep 2020 16:00:47
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:00:47

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 3'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:07', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd6ab15-f4af-4a1d-9cce-3c9320814af6' User entered 'Yes (Y)'	System	30 Sep 2020 16:03:07
	System	30 Sep 2020 16:03:07

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd6ab15-f4af-4a1d-9cce-3c9320814af6' User entered '99.6'	System	30 Sep 2020 16:03:07
	System	30 Sep 2020 16:03:07

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:15', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd6ab15-f4af-4a1d-9cce-3c9320814af6'	System	30 Sep 2020 16:03:07
User entered 'No (N)'	System	30 Sep 2020 16:03:07

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd6ab15-f4af-4a1d-9cce-3c9320814af6' User entered '30 Sep 2020 12:02'	System	30 Sep 2020 16:03:07
	System	30 Sep 2020 16:03:07

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 4'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '52574e4a-8ffe-4f94-962b-f9a60b517570' User entered 'Yes (Y)'	System	01 Oct 2020 16:24:26
	System	01 Oct 2020 16:24:26

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '52574e4a-8ffe-4f94-962b-f9a60b517570' User entered '96.3'	System	01 Oct 2020 16:24:26
	System	01 Oct 2020 16:24:26

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:38', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '52574e4a-8ffe-4f94-962b-f9a60b517570'	System	01 Oct 2020 16:24:26
User entered 'No (N)'	System	01 Oct 2020 16:24:26

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:43', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '52574e4a-8ffe-4f94-962b-f9a60b517570' User entered '01 Oct 2020 12:23'	System	01 Oct 2020 16:24:26
	System	01 Oct 2020 16:24:26

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 5'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:01:58', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9a993877-d1ed-4ef5-bafd-4ad213e52b25' User entered 'Yes (Y)'	System	02 Oct 2020 16:02:30
	System	02 Oct 2020 16:02:30

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9a993877-d1ed-4ef5-bafd-4ad213e52b25' User entered '97.5'	System	02 Oct 2020 16:02:30
	System	02 Oct 2020 16:02:30

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9a993877-d1ed-4ef5-bafd-4ad213e52b25'	System	02 Oct 2020 16:02:30
User entered 'No (N)'	System	02 Oct 2020 16:02:30

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:07', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9a993877-d1ed-4ef5-bafd-4ad213e52b25' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 16:02:30
	System	02 Oct 2020 16:02:30

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 6'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dc3185d8-336a-45bb-8d94-d3d39763bfa1' User entered 'Yes (Y)'	System	03 Oct 2020 16:02:13
	System	03 Oct 2020 16:02:13

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dc3185d8-336a-45bb-8d94-d3d39763bfa1' User entered '97.9'	System	03 Oct 2020 16:02:13
	System	03 Oct 2020 16:02:13

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dc3185d8-336a-45bb-8d94-d3d39763bfa1'	System	03 Oct 2020 16:02:13
User entered 'No (N)'	System	03 Oct 2020 16:02:13

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:41', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dc3185d8-336a-45bb-8d94-d3d39763bfa1' User entered '03 Oct 2020 12:01'	System	03 Oct 2020 16:02:13
	System	03 Oct 2020 16:02:13

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 7'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:17', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4621751e-4bf1-433b-94fb-a0534b64d6f5' User entered 'Yes (Y)'	System	04 Oct 2020 16:48:31
	System	04 Oct 2020 16:48:31

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:22', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4621751e-4bf1-433b-94fb-a0534b64d6f5' User entered '96.9'	System	04 Oct 2020 16:48:31
	System	04 Oct 2020 16:48:31

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4621751e-4bf1-433b-94fb-a0534b64d6f5'	System	04 Oct 2020 16:48:31
User entered 'No (N)'	System	04 Oct 2020 16:48:31

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4621751e-4bf1-433b-94fb-a0534b64d6f5' User entered '04 Oct 2020 12:48'	System	04 Oct 2020 16:48:31
	System	04 Oct 2020 16:48:31

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:05', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b03be17f-161e-4771-a3b3-647fa2d60bc7'	System	28 Sep 2020 14:06:19
User entered 'None (1)'	System	28 Sep 2020 14:06:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:07', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b03be17f-161e-4771-a3b3-647fa2d60bc7' User entered 'No (N)'	System	28 Sep 2020 14:06:19
	System	28 Sep 2020 14:06:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:10', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b03be17f-161e-4771-a3b3-647fa2d60bc7' User entered 'No (N)'	System	28 Sep 2020 14:06:19
	System	28 Sep 2020 14:06:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b03be17f-161e-4771-a3b3-647fa2d60bc7'	System	28 Sep 2020 14:06:19
User entered 'None (1)'	System	28 Sep 2020 14:06:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:17', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b03be17f-161e-4771-a3b3-647fa2d60bc7' User entered '28 Sep 2020 10:06'	System	28 Sep 2020 14:06:19
	System	28 Sep 2020 14:06:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 09:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 12:29'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:30:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '99dec380-83fd-4a61-ad9d-d0eca680707c'	System	28 Sep 2020 17:30:19
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 17:30:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:30:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '99dec380-83fd-4a61-ad9d-d0eca680707c' User entered 'No (N)'	System	28 Sep 2020 17:30:19
	System	28 Sep 2020 17:30:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:30:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '99dec380-83fd-4a61-ad9d-d0eca680707c' User entered 'No (N)'	System	28 Sep 2020 17:30:19
	System	28 Sep 2020 17:30:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:30:14', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '99dec380-83fd-4a61-ad9d-d0eca680707c' User entered 'None (1)'	System	28 Sep 2020 17:30:19
	System	28 Sep 2020 17:30:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:30:17', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '99dec380-83fd-4a61-ad9d-d0eca680707c' User entered '28 Sep 2020 13:30'	System	28 Sep 2020 17:30:19
	System	28 Sep 2020 17:30:19

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 2'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '56c35b1b-17df-4569-a650-e9100549dd7c'	System	29 Sep 2020 16:01:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	29 Sep 2020 16:01:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '56c35b1b-17df-4569-a650-e9100549dd7c' User entered 'No (N)'	System	29 Sep 2020 16:01:29
	System	29 Sep 2020 16:01:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:00:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '56c35b1b-17df-4569-a650-e9100549dd7c' User entered 'No (N)'	System	29 Sep 2020 16:01:29
	System	29 Sep 2020 16:01:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:01', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '56c35b1b-17df-4569-a650-e9100549dd7c' User entered 'None (1)'	System	29 Sep 2020 16:01:29
	System	29 Sep 2020 16:01:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '56c35b1b-17df-4569-a650-e9100549dd7c' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 16:01:29
	System	29 Sep 2020 16:01:29

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 3'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bdf989a3-fc4b-4572-a817-9a22e424796f'	System	30 Sep 2020 16:03:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Sep 2020 16:03:37

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bdf989a3-fc4b-4572-a817-9a22e424796f' User entered 'No (N)'	System	30 Sep 2020 16:03:37
	System	30 Sep 2020 16:03:37

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:38', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bdf989a3-fc4b-4572-a817-9a22e424796f' User entered 'No (N)'	System	30 Sep 2020 16:03:37
	System	30 Sep 2020 16:03:37

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:40', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bdf989a3-fc4b-4572-a817-9a22e424796f' User entered 'None (1)'	System	30 Sep 2020 16:03:37
	System	30 Sep 2020 16:03:37

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:44', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'bdf989a3-fc4b-4572-a817-9a22e424796f' User entered '30 Sep 2020 12:02'	System	30 Sep 2020 16:03:37
	System	30 Sep 2020 16:03:37

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 4'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c516ebe-69bf-48e1-b80d-8d8b06b9b9b7' User entered 'None (1)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:50', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c516ebe-69bf-48e1-b80d-8d8b06b9b9b7' User entered 'No (N)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:53', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c516ebe-69bf-48e1-b80d-8d8b06b9b9b7' User entered 'No (N)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c516ebe-69bf-48e1-b80d-8d8b06b9b9b7' User entered 'None (1)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:23:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c516ebe-69bf-48e1-b80d-8d8b06b9b9b7' User entered '01 Oct 2020 12:23'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 5'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4e2dd551-c7b4-4cfc-a44e-9e0fd15f3f45'	System	02 Oct 2020 16:02:48
User entered 'None (1)'	System	02 Oct 2020 16:02:48

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4e2dd551-c7b4-4cfc-a44e-9e0fd15f3f45'	System	02 Oct 2020 16:02:48
User entered 'No (N)'	System	02 Oct 2020 16:02:48

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4e2dd551-c7b4-4cfc-a44e-9e0fd15f3f45'	System	02 Oct 2020 16:02:48
User entered 'No (N)'	System	02 Oct 2020 16:02:48

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4e2dd551-c7b4-4cfc-a44e-9e0fd15f3f45'	System	02 Oct 2020 16:02:48
User entered 'None (1)'	System	02 Oct 2020 16:02:48

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:22', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '4e2dd551-c7b4-4cfc-a44e-9e0fd15f3f45' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 16:02:48
	System	02 Oct 2020 16:02:48

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 6'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:49', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '120e3647-6a0e-4260-9089-b908e1103f7f' User entered 'None (1)'	System	03 Oct 2020 16:02:25
	System	03 Oct 2020 16:02:25

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:52', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '120e3647-6a0e-4260-9089-b908e1103f7f' User entered 'No (N)'	System	03 Oct 2020 16:02:25
	System	03 Oct 2020 16:02:25

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '120e3647-6a0e-4260-9089-b908e1103f7f' User entered 'No (N)'	System	03 Oct 2020 16:02:25
	System	03 Oct 2020 16:02:25

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '120e3647-6a0e-4260-9089-b908e1103f7f' User entered 'None (1)'	System	03 Oct 2020 16:02:25
	System	03 Oct 2020 16:02:25

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:01:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '120e3647-6a0e-4260-9089-b908e1103f7f' User entered '03 Oct 2020 12:01'	System	03 Oct 2020 16:02:25
	System	03 Oct 2020 16:02:25

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 7'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '935b261a-1a85-4a15-93ad-747d000b91e3'	System	04 Oct 2020 16:48:43
User entered 'None (1)'	System	04 Oct 2020 16:48:43

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '935b261a-1a85-4a15-93ad-747d000b91e3' User entered 'No (N)'	System	04 Oct 2020 16:48:43
	System	04 Oct 2020 16:48:43

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:35', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '935b261a-1a85-4a15-93ad-747d000b91e3' User entered 'No (N)'	System	04 Oct 2020 16:48:43
	System	04 Oct 2020 16:48:43

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '935b261a-1a85-4a15-93ad-747d000b91e3'	System	04 Oct 2020 16:48:43
User entered 'None (1)'	System	04 Oct 2020 16:48:43

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '935b261a-1a85-4a15-93ad-747d000b91e3' User entered '04 Oct 2020 12:48'	System	04 Oct 2020 16:48:43
	System	04 Oct 2020 16:48:43

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:30', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:32', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:34', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'None (0)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered 'No (N)'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T10:06:39', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9db7245c-c803-44b8-a988-030080a8a37e' User entered '28 Sep 2020 10:06'	System	28 Sep 2020 14:06:44
	System	28 Sep 2020 14:06:44

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 09:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 12:29'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:14', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:21', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:24', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:26', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'None (0)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:28', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered 'No (N)'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-28T13:33:30', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c76488bb-707b-4c3b-9ead-0e6872aabc34' User entered '28 Sep 2020 13:33'	System	28 Sep 2020 17:33:36
	System	28 Sep 2020 17:33:36

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 2'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'None (0)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'None (0)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'No interference with activity (1)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'No interference with activity (1)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'None (0)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'None (0)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered 'No (N)'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-29T12:01:40', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'dfd502e6-5d1c-4069-b982-aae62aae0fef' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 16:02:24
	System	29 Sep 2020 16:02:24

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 3'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:48', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'None (0)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:50', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'None (0)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:53', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'None (0)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:55', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'None (0)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:02:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'None (0)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:03:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c'	System	30 Sep 2020 16:03:54
User entered 'No interference with activity (1)'	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:03:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered 'No (N)'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-09-30T12:03:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '219e3e37-2cc2-4fe6-b054-981de8028f0c' User entered '30 Sep 2020 12:03'	System	30 Sep 2020 16:03:54
	System	30 Sep 2020 16:03:54

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 4'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:04', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:06', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:08', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:10', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'None (0)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:17', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered 'No (N)'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-01T12:24:22', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'ed6c3a22-db02-470a-80a1-2ff28803f18a' User entered '01 Oct 2020 12:24'	System	01 Oct 2020 16:24:27
	System	01 Oct 2020 16:24:27

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 5'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:28', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:31', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'None (0)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:37', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered 'No (N)'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-02T12:02:40', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'c640e185-9c4a-4b82-9510-a26ae67e2457' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 16:03:01
	System	02 Oct 2020 16:03:01

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 6'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:03', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:05', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:07', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:08', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:10', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'None (0)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered 'No (N)'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-03T12:02:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e7ca6578-2d46-41e9-8ef5-bb9d42ca2128' User entered '03 Oct 2020 12:02'	System	03 Oct 2020 16:02:45
	System	03 Oct 2020 16:02:45

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	28 Sep 2020 13:41:42
User entered 'Day 7'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:44', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:48', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:50', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:52', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:54', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'None (0)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:48:58', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered 'No (N)'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-10-04T12:49:01', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '449f2b7d-c23f-4019-af95-8b8967faa57c' User entered '04 Oct 2020 12:49'	System	04 Oct 2020 16:49:04
	System	04 Oct 2020 16:49:04

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 13:41:42

US3522513

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 13:41:42

US3522513

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Oct 2020 16:04:30
User entered 'Yes (Y)'	Kristin Eis (b) (4)	05 Oct 2020 15:57:41
	(b) (4)	

US3522513

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered '05 Oct 2020'	Kristin Eis (b) (4)	05 Oct 2020 15:57:41

US3522513

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Kristin Eis (b) (4)	05 Oct 2020 16:04:30
User entered empty.	(b) (4)	
	Kristin Eis (b) (4)	05 Oct 2020 15:57:41
	(b) (4)	

US3522513

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:27:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Patient had pain/ soreness around the injection site the day after the injection 9/29, took two 400mg Tylenols tablets. Patients soreness went away the next day.' reason for change: Data Entry Error	(b) (4)	
	Kristin Eis (b) (4)	05 Oct 2020 16:04:30
	(b) (4)	
User entered empty.	Kristin Eis (b) (4)	05 Oct 2020 15:57:41
	(b) (4)	

US3522513

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	Kristin Eis (b) (4)	05 Oct 2020 16:04:34

US3522513

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'I'	System	05 Oct 2020 16:04:34

US3522513

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:07:52

US3522513

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:07:52

US3522513

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 14:07:52

US3522513

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'See source. 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)	12 Oct 2020 14:07:52

US3522513

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:07:57

US3522513

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'I'	System	12 Oct 2020 14:07:57

US3522513

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:29:28

US3522513

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:29:28

US3522513

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:28

US3522513

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:20
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
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)	19 Oct 2020 15:29:28

US3522513

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:29:33

US3522513

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'I'	System	19 Oct 2020 15:29:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:47:52

US3522513

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '26 Oct 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:47:52

US3522513

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[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 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:28:33
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:47:52

US3522513

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'VISIT3'	System	26 Oct 2020 11:47:52

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '26 Oct 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '07:20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '26 Oct 2020 07:20'	System	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '97.9' F	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '75'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'bpm'	System	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '14'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'breaths/min'	System	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '108'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '70'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'mmHg'	System	26 Oct 2020 11:48:33

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32

US3522513

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32

US3522513

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	26 Oct 2020 11:48:43

US3522513

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '26 Oct 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:48:43

US3522513

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:49:00

US3522513

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '26 Oct 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:49:00

US3522513

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered '07:30'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:49:00

US3522513

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered '26 Oct 2020 07:30'	System	26 Oct 2020 11:49:00

US3522513

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:29:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:09:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	26 Oct 2020 11:49:07

US3522513

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'I'	System	26 Oct 2020 11:49:07

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 64'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-02T07:59:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '88669a8f-4d20-4983-a969-5f449d4544c6'	System	02 Nov 2020 12:59:18
User entered 'No (N)'	System	02 Nov 2020 12:59:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-02T07:59:10', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '88669a8f-4d20-4983-a969-5f449d4544c6'	System	02 Nov 2020 12:59:18
User entered 'No (N)'	System	02 Nov 2020 12:59:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-02T07:59:15', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '88669a8f-4d20-4983-a969-5f449d4544c6' User entered '02 Nov 2020 07:59:15'	System	02 Nov 2020 12:59:18
	System	02 Nov 2020 12:59:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 71'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-09T00:06:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0cba813-9ee5-48b1-8849-31aef72eeca3'	System	09 Nov 2020 05:06:18
User entered 'No (N)'	System	09 Nov 2020 05:06:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-09T00:06:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0cba813-9ee5-48b1-8849-31aef72eeca3'	System	09 Nov 2020 05:06:18
User entered 'No (N)'	System	09 Nov 2020 05:06:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-09T00:06:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f0cba813-9ee5-48b1-8849-31aef72eeca3' User entered '09 Nov 2020 00:06:16'	System	09 Nov 2020 05:06:18
	System	09 Nov 2020 05:06:18

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered 'Day 78'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-17T09:09:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a65ae0a6-a1eb-4f72-8073-9feb5396ffe8'	System	17 Nov 2020 14:09:31
User entered 'No (N)'	System	17 Nov 2020 14:09:31

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-17T09:09:21', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a65ae0a6-a1eb-4f72-8073-9feb5396ffe8'	System	17 Nov 2020 14:09:31
User entered 'No (N)'	System	17 Nov 2020 14:09:31

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-17T09:09:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a65ae0a6-a1eb-4f72-8073-9feb5396ffe8' User entered '17 Nov 2020 09:09:25'	System	17 Nov 2020 14:09:31
	System	17 Nov 2020 14:09:31

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 12:53:01

US3522513

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:53:45
Data entry locked.	System	02 Sep 2020 12:53:01
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 12:53:01

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-22T14:01:29', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51d88fea-e01e-4b71-825d-9aee60c16677'	System	22 Nov 2020 19:01:43
User entered 'No (N)'	System	22 Nov 2020 19:01:43

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-22T14:01:33', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51d88fea-e01e-4b71-825d-9aee60c16677'	System	22 Nov 2020 19:01:43
User entered 'No (N)'	System	22 Nov 2020 19:01:43

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-22T14:01:36', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '51d88fea-e01e-4b71-825d-9aee60c16677' User entered '22 Nov 2020 14:01:36'	System	22 Nov 2020 19:01:43
	System	22 Nov 2020 19:01:43

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-27T09:29:52', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '1a33bfc2-6fa2-4e14-8d1b-51075c08a258'	System	27 Nov 2020 14:30:06
User entered 'No (N)'	System	27 Nov 2020 14:30:06

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-27T09:29:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '1a33bfc2-6fa2-4e14-8d1b-51075c08a258'	System	27 Nov 2020 14:30:06
User entered 'No (N)'	System	27 Nov 2020 14:30:06

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-11-27T09:30:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '1a33bfc2-6fa2-4e14-8d1b-51075c08a258' User entered '27 Nov 2020 09:30:02'	System	27 Nov 2020 14:30:06
	System	27 Nov 2020 14:30:06

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-05T03:42:52', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'df13eb00-2cf6-482e-a12d-93e06f8a4e49'	System	05 Dec 2020 08:43:03
User entered 'No (N)'	System	05 Dec 2020 08:43:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-05T03:42:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'df13eb00-2cf6-482e-a12d-93e06f8a4e49'	System	05 Dec 2020 08:43:03
User entered 'No (N)'	System	05 Dec 2020 08:43:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-05T03:42:59', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'df13eb00-2cf6-482e-a12d-93e06f8a4e49' User entered '05 Dec 2020 03:42:59'	System	05 Dec 2020 08:43:03
	System	05 Dec 2020 08:43:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 07:31:54
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'related to right knee injury that she already addressed with staff twice, but the start date was incorrect, corrected "right knee injury" AE start date (approximate)' (Site from DM).	Yaman Ahmed (b) (4)	16 Mar 2021 21:33:11
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:07:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:50:51', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7'	System	12 Dec 2020 02:51:34
User entered 'Yes (Y)'	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:50:57', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7' User entered 'No (N)'	System	12 Dec 2020 02:51:34
	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:51:03', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7' User entered 'No (N)'	System	12 Dec 2020 02:51:34
	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:51:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7' User entered 'Yes (Y)'	System	12 Dec 2020 02:51:34
	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Please 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:51:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7'	System	12 Dec 2020 02:51:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-11T21:51:24', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '18cf24d1-410a-4b29-b821-176d3e865da7' User entered '11 Dec 2020 21:51:24'	System	12 Dec 2020 02:51:34
	System	12 Dec 2020 02:51:34

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-18T10:53:56', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8c8327e7-3003-4a2e-ae5a-85ea09b6f5f4'	System	18 Dec 2020 15:54:31
User entered 'No (N)'	System	18 Dec 2020 15:54:31

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-18T10:54:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8c8327e7-3003-4a2e-ae5a-85ea09b6f5f4'	System	18 Dec 2020 15:54:31
User entered 'No (N)'	System	18 Dec 2020 15:54:31

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-18T10:54:26', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8c8327e7-3003-4a2e-ae5a-85ea09b6f5f4' User entered '18 Dec 2020 10:54:26'	System	18 Dec 2020 15:54:31
	System	18 Dec 2020 15:54:31

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-25T01:30:38', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a1b2b3e4-55a4-4b78-a1e6-a7b9c0218abb' User entered 'No (N)'	System	25 Dec 2020 06:30:46
	System	25 Dec 2020 06:30:46

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-25T01:30:41', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a1b2b3e4-55a4-4b78-a1e6-a7b9c0218abb' User entered 'No (N)'	System	25 Dec 2020 06:30:46
	System	25 Dec 2020 06:30:46

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2020-12-25T01:30:44', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a1b2b3e4-55a4-4b78-a1e6-a7b9c0218abb' User entered '25 Dec 2020 01:30:44'	System	25 Dec 2020 06:30:46
	System	25 Dec 2020 06:30:46

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-01T08:11:55', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a10769c3-047a-4e9e-a5dc-cb1a88a7fd6d' User entered 'No (N)'	System	01 Jan 2021 13:12:14
	System	01 Jan 2021 13:12:14

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-01T08:12:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a10769c3-047a-4e9e-a5dc-cb1a88a7fd6d' User entered 'No (N)'	System	01 Jan 2021 13:12:14

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-01T08:12:12', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'a10769c3-047a-4e9e-a5dc-cb1a88a7fd6d' User entered '01 Jan 2021 08:12:12'	System	01 Jan 2021 13:12:14
	System	01 Jan 2021 13:12:14

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-08T19:01:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '172dd182-8c60-4942-9024-13558782b038' User entered 'No (N)'	System	09 Jan 2021 00:01:25
	System	09 Jan 2021 00:01:25

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-08T19:01:20', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '172dd182-8c60-4942-9024-13558782b038'	System	09 Jan 2021 00:01:25
User entered 'No (N)'	System	09 Jan 2021 00:01:25

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-08T19:01:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '172dd182-8c60-4942-9024-13558782b038' User entered '08 Jan 2021 19:01:23'	System	09 Jan 2021 00:01:25
	System	09 Jan 2021 00:01:25

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-18T17:59:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c6ccd0e-20cc-43ef-8a39-f271abca0596'	System	18 Jan 2021 22:59:24
User entered 'No (N)'	System	18 Jan 2021 22:59:24

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-18T17:59:19', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c6ccd0e-20cc-43ef-8a39-f271abca0596'	System	18 Jan 2021 22:59:24
User entered 'No (N)'	System	18 Jan 2021 22:59:24

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-18T17:59:22', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9c6ccd0e-20cc-43ef-8a39-f271abca0596' User entered '18 Jan 2021 17:59:22'	System	18 Jan 2021 22:59:24
	System	18 Jan 2021 22:59:24

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-24T18:27:40', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '3c66804f-8fb1-4ab6-a194-e61f4bc8bbd6'	System	24 Jan 2021 23:27:49
User entered 'No (N)'	System	24 Jan 2021 23:27:49

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-24T18:27:43', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '3c66804f-8fb1-4ab6-a194-e61f4bc8bbd6'	System	24 Jan 2021 23:27:49
User entered 'No (N)'	System	24 Jan 2021 23:27:49

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-24T18:27:46', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '3c66804f-8fb1-4ab6-a194-e61f4bc8bbd6' User entered '24 Jan 2021 18:27:46'	System	24 Jan 2021 23:27:49

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-29T07:43:23', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd0d1b89b-3dc9-4715-88fd-4725e97516b4'	System	29 Jan 2021 12:43:33
User entered 'No (N)'	System	29 Jan 2021 12:43:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-29T07:43:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd0d1b89b-3dc9-4715-88fd-4725e97516b4'	System	29 Jan 2021 12:43:33
User entered 'No (N)'	System	29 Jan 2021 12:43:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-01-29T07:43:30', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd0d1b89b-3dc9-4715-88fd-4725e97516b4' User entered '29 Jan 2021 07:43:30'	System	29 Jan 2021 12:43:33
	System	29 Jan 2021 12:43:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-05T15:38:09', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8fc5fff7-ef10-44a0-9ef9-9809113b5b67'	System	05 Feb 2021 20:38:30
User entered 'Yes (Y)'	System	05 Feb 2021 20:38:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-05T15:38:11', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8fc5fff7-ef10-44a0-9ef9-9809113b5b67'	System	05 Feb 2021 20:38:30
User entered 'No (N)'	System	05 Feb 2021 20:38:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-05T15:38:15', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8fc5fff7-ef10-44a0-9ef9-9809113b5b67'	System	05 Feb 2021 20:38:30
User entered 'No (N)'	System	05 Feb 2021 20:38:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-05T15:38:25', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8fc5fff7-ef10-44a0-9ef9-9809113b5b67'	System	05 Feb 2021 20:38:30
User entered 'No (N)'	System	05 Feb 2021 20:38:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-05T15:38:27', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '8fc5fff7-ef10-44a0-9ef9-9809113b5b67' User entered '05 Feb 2021 15:38:27'	System	05 Feb 2021 20:38:30
	System	05 Feb 2021 20:38:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-14T12:03:13', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e070d3ea-17e6-42d5-a048-2ceb4e4123ef' User entered 'No (N)'	System	14 Feb 2021 17:08:52
	System	14 Feb 2021 17:08:52

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-14T12:03:16', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e070d3ea-17e6-42d5-a048-2ceb4e4123ef' User entered 'No (N)'	System	14 Feb 2021 17:08:52

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-14T12:03:18', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e070d3ea-17e6-42d5-a048-2ceb4e4123ef' User entered '14 Feb 2021 12:03:18'	System	14 Feb 2021 17:08:52
	System	14 Feb 2021 17:08:52

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-21T10:30:58', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cbf9dad-32be-4a68-a290-02989009f498'	System	21 Feb 2021 15:31:11
User entered 'No (N)'	System	21 Feb 2021 15:31:11

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-21T10:31:02', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cbf9dad-32be-4a68-a290-02989009f498' User entered 'No (N)'	System	21 Feb 2021 15:31:11

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-21T10:31:05', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9cbf9dad-32be-4a68-a290-02989009f498' User entered '21 Feb 2021 10:31:05'	System	21 Feb 2021 15:31:11
	System	21 Feb 2021 15:31:11

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-28T12:10:15-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f7d27631-cfec-40de-a93f-21f02959dfd9' User entered 'No (N)'	System	28 Feb 2021 17:14:33
	System	28 Feb 2021 17:14:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-28T12:10:19-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f7d27631-cfec-40de-a93f-21f02959dfd9' User entered 'No (N)'	System	28 Feb 2021 17:14:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-28T12:10:21-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'f7d27631-cfec-40de-a93f-21f02959dfd9' User entered '28 Feb 2021 17:10:21'	System	28 Feb 2021 17:14:33
	System	28 Feb 2021 17:14:33

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-07T10:11:52-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '68fd9c8e-2d4c-4e1f-b1d0-5f37ba461ddc'	System	07 Mar 2021 15:12:03
User entered 'No (N)'	System	07 Mar 2021 15:12:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-07T10:11:55-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '68fd9c8e-2d4c-4e1f-b1d0-5f37ba461ddc'	System	07 Mar 2021 15:12:03
User entered 'No (N)'	System	07 Mar 2021 15:12:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-07T10:11:59-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '68fd9c8e-2d4c-4e1f-b1d0-5f37ba461ddc'	System	07 Mar 2021 15:12:03
User entered '07 Mar 2021 10:11:59'	System	07 Mar 2021 15:12:03

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-14T13:09:34-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '93b162e8-d657-43c9-b718-7c5a8c9efe9a' User entered 'No (N)'	System	14 Mar 2021 17:09:58
	System	14 Mar 2021 17:09:58

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-14T13:09:37-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '93b162e8-d657-43c9-b718-7c5a8c9efe9a'	System	14 Mar 2021 17:09:58
User entered 'No (N)'	System	14 Mar 2021 17:09:58

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-14T13:09:40-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '93b162e8-d657-43c9-b718-7c5a8c9efe9a' User entered '14 Mar 2021 13:09:40'	System	14 Mar 2021 17:09:58
	System	14 Mar 2021 17:09:58

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-21T12:00:45-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9e8dc410-baa0-4e9e-8915-e18bc52b5cb8'	System	21 Mar 2021 16:02:27
User entered 'No (N)'	System	21 Mar 2021 16:02:27

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-21T12:00:51-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9e8dc410-baa0-4e9e-8915-e18bc52b5cb8' User entered 'No (N)'	System	21 Mar 2021 16:02:27
	System	21 Mar 2021 16:02:27

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-21T12:00:54-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '9e8dc410-baa0-4e9e-8915-e18bc52b5cb8' User entered '21 Mar 2021 12:00:54'	System	21 Mar 2021 16:02:27
	System	21 Mar 2021 16:02:27

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-28T12:02:14-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76d42157-babd-42be-a951-a833ab912d99'	System	28 Mar 2021 16:06:30
User entered 'No (N)'	System	28 Mar 2021 16:06:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-28T12:02:17-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76d42157-babd-42be-a951-a833ab912d99'	System	28 Mar 2021 16:06:30
User entered 'No (N)'	System	28 Mar 2021 16:06:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-03-28T12:02:19-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '76d42157-babd-42be-a951-a833ab912d99'	System	28 Mar 2021 16:06:30
User entered '28 Mar 2021 12:02:19'	System	28 Mar 2021 16:06:30

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-02T00:02:16-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '67474f31-8352-4bbf-a049-df4b3029943b' User entered 'No (N)'	System	02 Apr 2021 04:04:04
	System	02 Apr 2021 04:04:04

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-02T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '67474f31-8352-4bbf-a049-df4b3029943b' User entered 'No (N)'	System	02 Apr 2021 04:04:04
	System	02 Apr 2021 04:04:04

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-02T00:02:23-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '67474f31-8352-4bbf-a049-df4b3029943b' User entered '02 Apr 2021 00:02:23'	System	02 Apr 2021 04:04:04
	System	02 Apr 2021 04:04:04

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-09T02:10:27-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2f961abd-35e9-4b52-830e-071f20ebe03e' User entered 'No (N)'	System	09 Apr 2021 06:10:38
	System	09 Apr 2021 06:10:38

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-09T02:10:30-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2f961abd-35e9-4b52-830e-071f20ebe03e' User entered 'No (N)'	System	09 Apr 2021 06:10:38
	System	09 Apr 2021 06:10:38

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-09T02:10:32-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '2f961abd-35e9-4b52-830e-071f20ebe03e' User entered '09 Apr 2021 02:10:32'	System	09 Apr 2021 06:10:38
	System	09 Apr 2021 06:10:38

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-16T12:29:09-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b3b283ff-6b38-436c-ba3e-c574bd3c6001' User entered 'No (N)'	System	16 Apr 2021 16:29:20
	System	16 Apr 2021 16:29:20

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-16T12:29:11-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b3b283ff-6b38-436c-ba3e-c574bd3c6001' User entered 'No (N)'	System	16 Apr 2021 16:29:20
	System	16 Apr 2021 16:29:20

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-16T12:29:14-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'b3b283ff-6b38-436c-ba3e-c574bd3c6001'	System	16 Apr 2021 16:29:20
User entered '16 Apr 2021 12:29:14'	System	16 Apr 2021 16:29:20

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-23T12:23:43-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd21c9e95-6792-413f-9d61-af0ccbdd1dde' User entered 'No (N)'	System	23 Apr 2021 16:23:53
	System	23 Apr 2021 16:23:53

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-23T12:23:46-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd21c9e95-6792-413f-9d61-af0ccbdd1dde' User entered 'No (N)'	System	23 Apr 2021 16:23:53
	System	23 Apr 2021 16:23:53

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-04-23T12:23:49-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'd21c9e95-6792-413f-9d61-af0ccbdd1dde' User entered '23 Apr 2021 12:23:49'	System	23 Apr 2021 16:23:53
	System	23 Apr 2021 16:23:53

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-05-02T10:04:05-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e168b7e0-a372-4ab3-aa41-ad587ab1dae7'	System	02 May 2021 14:04:15
User entered 'No (N)'	System	02 May 2021 14:04:15

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

Have you been exposed to someone with 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 (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-05-02T10:04:07-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e168b7e0-a372-4ab3-aa41-ad587ab1dae7'	System	02 May 2021 14:04:15
User entered 'No (N)'	System	02 May 2021 14:04:15

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-05-02T10:04:09-04:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: 'e168b7e0-a372-4ab3-aa41-ad587ab1dae7'	System	02 May 2021 14:04:15
User entered '02 May 2021 10:04:09'	System	02 May 2021 14:04:15

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:25:08

US3522513

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:25:08
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:25:08

US3522513

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:08

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 20:26:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-28T12:10:28-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '82f47f96-465e-42a5-84da-3f3e206e4380'	System	07 Mar 2021 15:11:47
User entered 'No (N)'	System	07 Mar 2021 15:11:47

US3522513

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:26:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CD6C576-20D1-4CE5-ADE0-528BE738FB3D)', Time: '2021-02-28T12:10:31-05:00', User OID: 'PatientReportedOutcome (US3522513)', ODM File OID: '82f47f96-465e-42a5-84da-3f3e206e4380' User entered '28 Feb 2021 17:10:31'	System	07 Mar 2021 15:11:47
	System	07 Mar 2021 15:11:47

US3522513

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:34
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:27:40

US3522513

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:34
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 15:27:40

US3522513

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:34
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:40

US3522513

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:34
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
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)	23 Nov 2020 15:27:40

US3522513

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:43

US3522513

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:26:32
User entered 'I'	System	23 Nov 2020 15:27:43

US3522513

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Dec 2020 16:21:41

US3522513

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '24 Dec 2020'	(b) (4), (b) (6)	24 Dec 2020 16:21:41

US3522513

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Dec 2020 16:21:41

US3522513

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:32:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
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)	24 Dec 2020 16:21:41

US3522513

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:33:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Dec 2020 16:21:50

US3522513

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
User entered 'I'	System	24 Dec 2020 16:21:50

US3522513

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:33:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:48:03

US3522513

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:33:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '26 Jan 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:48:03

US3522513

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:33:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:48:03

US3522513

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:33:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
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) Yaman Ahmed (b) (4)	26 Jan 2021 14:48:03

US3522513

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:34:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:48:08

US3522513

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
User entered 'I'	System	26 Jan 2021 14:48:08

US3522513

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:34:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:40:12

US3522513

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:34:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '23 Feb 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:40:12

US3522513

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:34:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:40:12

US3522513

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:34:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'R KNEE INJURY ON 24 DEC 2020; GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK. THEN F/U IN 05 FEB 2021, WAS GIVEN SAME NORCO FOR A WEEK AND TOLD THAT SHE NEEDS TOTAL KNEE REPLACEMENT (24 March)' reason for change: Data Entry Error	(b) (4)	
User entered 'Right knee injury on 24 Dec 2020; was given crutches, knee brace and Norco 10/325 for a week then went back in 05 Feb 2021 for a follow up and was given same Norco for a week and was told that she needs total knee replacement surgery' (non-conformant).	Yaman Ahmed (b) (4)	23 Feb 2021 15:43:17
	(b) (4)	23 Feb 2021 15:40:12

US3522513

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:35:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:43:23

US3522513

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:41:22
User entered 'I'	System	23 Feb 2021 15:43:23

US3522513

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:07
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:31:27

US3522513

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:07
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:31:27

US3522513

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[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 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:07
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:31:27

US3522513

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered 'VISIT4'	System	22 Mar 2021 17:31:27

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered empty.	System	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered empty.	System	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered empty.	System	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered empty.	System	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:55:23
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:48:24
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered empty.	System	31 Mar 2021 15:56:18

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20

US3522513

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:37
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 06:32:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20

US3522513

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:13
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:31:36

US3522513

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:13
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:31:36

US3522513

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:18
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:32:10

US3522513

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:18
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:32:10

US3522513

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:18
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered '13:30'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:32:10

US3522513

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered '22 Mar 2021 13:30'	System	22 Mar 2021 17:32:10

US3522513

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:35
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:23:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:32:17

US3522513

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:20
User entered 'I'	System	22 Mar 2021 17:32:17

US3522513

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:44
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	27 Apr 2021 14:01:38
	(b) (4)	

US3522513

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:44
	(b) (4)	
User entered '27 Apr 2021'	Yaman Ahmed (b) (4)	27 Apr 2021 14:01:38
	(b) (4)	

US3522513

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Yaman Ahmed (b) (4)	27 Apr 2021 14:01:38

US3522513

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:44
User entered 'left a voicemail message'	(b) (4) Yaman Ahmed (b) (4)	27 Apr 2021 14:01:38

US3522513

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:44
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	27 Apr 2021 14:01:42
	(b) (4)	

US3522513

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 14:01:42

US3522513

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:10:26

US3522513

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:10:26

US3522513

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:36:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Jan 2021 17:10:26

US3522513

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 17:10:26

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:24:41
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	17 Mar 2021 16:43:18
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:56:42

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:24:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sharon Mathys (b) (4)	17 Mar 2021 16:43:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:56:42

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
User entered empty.	System	28 Jan 2021 17:10:39

US3522513

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
User entered empty.	System	28 Jan 2021 17:10:39

US3522513

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:10:48

US3522513

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:10:48

US3522513

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '12:01'	(b) (4), (b) (6)	28 Jan 2021 17:10:48

US3522513

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
User entered '28 Jan 2021 12:01'	System	28 Jan 2021 17:10:48

US3522513

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:11:00

US3522513

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:11:00

US3522513

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '12:00'	(b) (4), (b) (6)	28 Jan 2021 17:11:00

US3522513

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:04
User entered '28 Jan 2021 12:00'	System	28 Jan 2021 17:11:00

US3522513

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:01:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:48
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:37:57
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:39:52
User closed query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 10:07:58
Query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:40:27
User entered 'Yes (Y)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:40:22
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:08:42
User entered 'No (N)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 17:32:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 17:45:26

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:26
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:36:43
User entered 'USA-US131-2021-mRNA-1273-P301000017'	System	29 Apr 2021 19:36:36
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 19:36:36

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:56:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:56:00
Data point term sent to Coder	System	23 Feb 2021 15:55:23
User entered 'Right knee injury'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:24:41
Signature has been broken.	Yaman Ahmed (b) (4)	16 Mar 2021 21:31:55
User entered '11 Dec 2020' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	16 Mar 2021 21:31:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '24 Dec 2020'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 07:32:24
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing and due for right total knee arthroplasty, see narrative note' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	17 Mar 2021 17:16:41
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:49:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:20
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:22
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 May 2021 11:58:03
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:09:13
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 13:56:49
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Apr 2021 13:56:02
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Apr 2021 13:56:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:56:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:56:02
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:56:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:56:02
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	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:09
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:11
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:09:26
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:54:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'I'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'I'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:49:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 18:13:54
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:13:51
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:53:05
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:53:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	29 Apr 2021 13:53:05
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:09:59
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 17:47:24
Signature has been broken.	Yaman Ahmed (b) (4)	30 Apr 2021 17:02:17
User entered 'RIGHT KNEE INJURY ON 11 DEC 2020, WITH ORTHOPEDIC FOLLOW UP ON 24 DEC 2020; WAS GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK THEN WENT BACK IN 05 FEB 2021 FOR A FOLLOW UP AND WAS GIVEN SAME NORCO FOR A WEEK AND WAS TOLD THAT SHE NEEDS TOTAL RIGHT KNEE REPLACEMENT (ARTHROPLASTY) SURGERY (24 MARCH 2021)... 30 APR 2021 UPDATE: SURGERY HAS NOT RECOVERED WELL, SO SHE'S DUE BACK ON 03 MAY 2021 FOR A REPEAT SURGERY (Manipulation under anesthesia per PCP note on 26 Apr 2021 in EMR). SHE IS STILL TAKING OXYCODONE AND ROBAXIN AS NEEDED TO MANAGE PAIN SINCE SURGERY. REVIEWED AND GRADED BY DR. KILGORE.' reason for change: New Information	Yaman Ahmed (b) (4)	30 Apr 2021 17:02:17
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 16:59:10
Signature has been broken.	Yaman Ahmed (b) (4)	30 Apr 2021 16:53:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'RIGHT KNEE INJURY ON 11 DEC 2020, WITH ORTHOPEDIC FOLLOW UP ON 24 DEC 2020; WAS GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK THEN WENT BACK IN 05 FEB 2021 FOR A FOLLOW UP AND WAS GIVEN SAME NORCO FOR A WEEK AND WAS TOLD THAT SHE NEEDS TOTAL RIGHT KNEE REPLACEMENT (ARTHROPLASTY) SURGERY (24 MARCH 2021)... 30 Apr 2021 update: surgery has not recovered well, so she's due back on 03 May 2021 for a repeat surgery. She is still taking Oxycodone and Robaxin as needed to manage pain since surgery. REVIEWED AND GRADED BY DR. KILGORE.' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	30 Apr 2021 16:53:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	29 Apr 2021 22:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:54:40
User entered 'RIGHT KNEE INJURY ON 11 DEC 2020, WITH ORTHOPEDIC FOLLOW UP ON 24 DEC 2020; WAS GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK THEN WENT BACK IN 05 FEB 2021 FOR A FOLLOW UP AND WAS GIVEN SAME NORCO FOR A WEEK AND WAS TOLD THAT SHE NEEDS TOTAL RIGHT KNEE REPLACEMENT (ARTHROPLASTY) SURGERY (24 MARCH 2021)	(b) (4), (b) (6)	29 Apr 2021 13:54:40
reviewed and graded by Dr. kilgore.' reason for change: Data Entry Error		
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	28 Apr 2021 20:47:44
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:08:48
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	27 Apr 2021 13:56:32
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	27 Apr 2021 13:56:32

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'RIGHT KNEE INJURY ON 11 Dec 2020, with orthopedic follow up on 24 DEC 2020; WAS GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK THEN WENT BACK IN 05 FEB 2021 FOR A FOLLOW UP AND WAS GIVEN SAME NORCO FOR A WEEK AND WAS TOLD THAT SHE NEEDS TOTAL RIGHT KNEE REPLACEMENT (ARTHROPLASTY) SURGERY (24 MARCH 2021)' reason for change: Data Entry Error DataPoint Verified.	Yaman Ahmed (b) (4) (b) (4)	27 Apr 2021 13:56:32
	(b) (4), (b) (6)	30 Mar 2021 23:38:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:24:41
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	17 Mar 2021 17:17:09
User entered 'RIGHT KNEE INJURY ON 24 DEC 2020; WAS GIVEN CRUTCHES, KNEE BRACE AND NORCO 10/325 FOR A WEEK THEN WENT BACK IN 05 FEB 2021 FOR A FOLLOW UP AND WAS GIVEN SAME NORCO FOR A WEEK AND WAS TOLD THAT SHE NEEDS TOTAL RIGHT KNEE REPLACEMENT (arthroplasty) SURGERY (24 MARCH 2021)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	17 Mar 2021 17:17:09
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:25:12
User entered 'Right knee injury on 24 Dec 2020; was given crutches, knee brace and Norco 10/325 for a week then went back in 05 Feb 2021 for a follow up and was given same Norco for a week and was told that she needs total knee replacement surgery (24 March 2021)'	Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:54:40
User entered '0'	System	23 Feb 2021 15:54:58

US3522513

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 15:54:58

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:48
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 11:01:44
Query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'some interference with activity' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 18:42:44
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:35:44

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:14:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:14:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	10 Nov 2020 21:14:24 10 Nov 2020 21:14:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:37:46
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 Sep 2020 12:37:46
Data point term sent to Coder User entered 'Robaxin'	System (b) (4), (b) (6)	02 Sep 2020 12:37:06 02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:08:33
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:14:18
User entered 'cervical ARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:14:10
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:18:15
User entered 'Arthritis'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '750'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'three times daily (TID)'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:58:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:58:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:58:01
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:36:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 12:36:23

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:37:46
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 Sep 2020 12:37:46
Data point term sent to Coder	System	02 Sep 2020 12:37:06
User entered 'Atorvastatin'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:43:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:43:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:43:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:37:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '10'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:43:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:43:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:43:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:37:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 12:37:01

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:38:51
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 Sep 2020 12:38:51
Data point term sent to Coder	System	02 Sep 2020 12:38:07
User entered 'valacyclovir'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:07:02
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:02:31
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Oct 2020 14:02:23
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:54:20
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:38:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:38:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:38:19
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:37:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'genital herpes'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '500'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:38:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:38:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 12:38:28
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:37:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 12:37:56

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Dec 2020 17:46:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 17:46:47
Data point term sent to Coder	System	22 Dec 2020 17:45:45
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 17:45:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 16:07:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 16:07:20
Data point term sent to Coder	System	05 Oct 2020 16:07:00
User entered 'Tylenol'	Kristin Eis (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN/SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN/SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 07:48:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN/SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN/SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'updated AE in chart to reflect e diary submitted by pt. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:47:05
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:45:10
User entered 'PAIN AT INJECTION SITE' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 17:45:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN/SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN/SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:45:18
Query ""Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN/SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN/SORENESS AT INJECTION SITE did not meet the AE reporting criteria.	(b) (4), (b) (6)	09 Dec 2020 16:45:14

Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.

Per DM CLR: Please review other frequency = Twice. Please review if this was given twice a day, twice within 2 days, etc. Review and update entry as appropriate."
' canceled (Site from DM).

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
User opened query ""Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN/SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN/SORENESS AT INJECTION SITE did not meet the AE reporting criteria. Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. Per DM CLR: Please review other frequency = Twice. Please review if this was given twice a day, twice within 2 days, etc. Review and update entry as appropriate." ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	09 Dec 2020 16:44:53
	(b) (4), (b) (6) (b) (4)	09 Dec 2020 01:56:23
User entered 'pain/soreness at injection site'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '650' reason for change: New Information	Alandra White (b) (4) (b) (4)	22 Oct 2020 19:37:38
User entered '400'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:45:10
User entered 'as needed (PRN)' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 17:45:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'other (OTHER)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User closed query 'Per DM CLR: Please review other frequency = Twice. Please review if this was given twice a day, twice within 2 days, etc. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 06:36:55
Query 'Per DM CLR: Please review other frequency = Twice. Please review if this was given twice a day, twice within 2 days, etc. Review and update entry as appropriate.' answered with 'updated information ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:47:37
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:45:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:45:10
User opened query 'Per DM CLR: Please review other frequency = Twice. Please review if this was given twice a day, twice within 2 days, etc. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:48:14
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'twice'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Oral (ORAL)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered empty.	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User closed query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Pain/Soreness at Injection Site which started 03 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 07:32:01
Query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Pain/Soreness at Injection Site which started 03 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'dates adjusted to reflect updated info based on e diary information provided' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:48:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:47:55
User entered '03 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 17:47:55
User opened query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Pain/Soreness at Injection Site which started 03 Sep 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:15:48
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '5 Sep 2020' reason for change: Data Entry Error	Alandra White (b) (4)	22 Oct 2020 19:37:38
User entered '29 Sep 2020'	(b) (4) Kristin Eis (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '0'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:47:55
User entered '04 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 17:47:55
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered '30 Sep 2020'	Kristin Eis (b) (4)	05 Oct 2020 16:06:35
	(b) (4)	

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:56:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	22 Oct 2020 19:37:38
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:06:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 15:58:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:58:00
Data point term sent to Coder	System	23 Feb 2021 15:57:28
User entered 'Norco'	Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Right knee injury'	Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '10/325'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'once daily (QD)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '24 Dec 2020'	Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '30 Dec 2020'	Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 15:56:35

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 16:00:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:00:05
Data point term sent to Coder	System	23 Feb 2021 15:59:29
User entered 'Norco'	Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Right knee injury'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '10/325'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '5 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '0'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '9 Feb 2021'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'No (N)'	Yaman Ahmed (b) (4)	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 15:58:45

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
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)	29 Apr 2021 13:55:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 13:55:56
Data point term sent to Coder	System	29 Apr 2021 13:45:38
User entered 'ASPIRIN'	(b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PREVENTION OF BLOOD CLOTS POST-RIGHT TOTAL KNEE REPLACEMENT'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '81'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 13:41:29

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 13:46:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 13:46:58
Data point term sent to Coder	System	29 Apr 2021 13:45:40
User entered 'TYLENOL'	(b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PAIN POST- RIGHT TOTAL KNEE REPLACEMENT'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '975'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 13:43:10

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 13:48:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 13:48:55
Data point term sent to Coder	System	29 Apr 2021 13:45:41
User entered 'OXYCODONE'	(b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PAIN POST RIGHT TOTAL KNEE REPLACEMENT'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '5-10'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'AS NEEDED EVERY 6 HOURS'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Apr 2021 13:45:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 13:45:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:45:14
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 13:45:09
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:45:09

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 14:15:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Apr 2021 14:15:59
Data point term sent to Coder	System	29 Apr 2021 13:49:36
User entered 'CELEBREX'	(b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PAIN POST RIGHT TOTAL KNEE REPLACEMENT'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '10'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'CRA-SS: Please confirm if med is ongoing. According to source stop date of 31Mar2021 is recorded in Medication list. ' (Site from CRA).	(b) (4), (b) (6)	04 May 2021 02:37:29
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 02:37:02
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 15:49:27
Query 'CRA-SS: Please confirm if med is ongoing. According to source stop date of 31Mar2021 is recorded in Medication list. ' answered with 'Corrected' (Site from CRA).	mayur ramesh (b) (4)	01 May 2021 13:12:25
Signature has been broken.	mayur ramesh (b) (4)	01 May 2021 13:11:45
User entered 'No (N)' reason for change: Data Entry Error	mayur ramesh (b) (4)	01 May 2021 13:11:45
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User opened query 'CRA-SS: Please confirm if med is ongoing. According to source stop date of 31Mar2021 is recorded in Medication list. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:02:24
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 02:37:17
User signature succeeded.	Marcus Zervos (b) (4)	03 May 2021 15:49:27
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	01 May 2021 13:12:42
DataPoint Un-verified.	mayur ramesh (b) (4)	01 May 2021 13:12:42
	(b) (4)	
Signature has been broken.	mayur ramesh (b) (4)	01 May 2021 13:12:42
	(b) (4)	
User entered '31 Mar 2021' reason for change: Per Query Resolution	mayur ramesh (b) (4)	01 May 2021 13:12:42
	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	01 May 2021 13:11:45
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 13:46:51

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 13:54:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 13:54:19
Data point term sent to Coder	System	29 Apr 2021 13:49:38
User entered 'GABAPENTIN'	(b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PAIN POST TOTAL RIGHT KNEE REPLACEMENT'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '300'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'PRESCRIBED AS 300 MG THREE TIMES A DAY BUT PATIENT TAKES IT ONCE NIGHTLY INSTEAD.'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:03:18
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:48:48

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:01:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:48
Query 'Please provide details of Fine needle aspiration performed on 30NOV2020. Thank you' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:54:16
Query 'Per source please provide details of thyroid screening on 27Oct2020' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:53:10
User opened query 'Please provide details of Fine needle aspiration performed on 30NOV2020. Thank you' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:43:03
User opened query 'Per source please provide details of thyroid screening on 27Oct2020' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:38:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:38:23
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Yes (Y)' reason for change: New Information	Yaman Ahmed (b) (4)	26 Jan 2021 14:50:31
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:39:10

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:43:12
User closed query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:42:59
Query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' answered with 'See redcap source unscheduled communications for path reports and updated dates' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 18:11:25
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:19
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 18:08:19
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 18:08:19
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:37
User opened query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:46:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '11 Dec 2020'	(b) (4)	
	Yaman Ahmed (b) (4)	26 Jan 2021 14:51:32
	(b) (4)	

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'right-sided thyroid nodule FNA biopsy'	(b) (4) Yaman Ahmed (b) (4)	26 Jan 2021 14:51:32

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Medical History (MH)'	Yaman Ahmed (b) (4)	26 Jan 2021 14:51:32

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:08

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	26 Jan 2021 14:51:32

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:22
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:09:03
User closed query 'It is stated that it was repeated one month after initial performed on 11DEC2021. However, no specific date has been given. If this is the date performed please addend source accordingly. If dte not known, please update to Unknown, JAN 2021.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 22:08:49
Query 'It is stated that it was repeated one month after initial performed on 11DEC2021. However, no specific date has been given. If this is the date performed please addend source accordingly. If dte not known, please update to Unknown, JAN 2021.' answered with 'See redcap source unscheduled communications for path reports and updated dates' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 18:11:33
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 18:08:04
User entered '5 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 18:08:04
User opened query 'It is stated that it was repeated one month after initial performed on 11DEC2021. However, no specific date has been given. If this is the date performed please addend source accordingly. If dte not known, please update to Unknown, JAN 2021.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:48:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:25:12
User entered '11 Jan 2021'	Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:52:33

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:22
User closed query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 22:08:36
Query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' answered with 'See redcap source unscheduled communications for path reports and updated dates' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 18:11:35
User opened query 'Although documented in REDCAP as being performed, kindly provide details of biopsy in EPIC for CRA review of procedure and results.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:48:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'right-sided thyroid nodule FNA biopsy'	(b) (4)	
	Yaman Ahmed (b) (4)	26 Jan 2021 14:52:33
	(b) (4)	

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Jan 2021 14:52:33

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:46:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	26 Jan 2021 14:52:33
	(b) (4)	

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:52:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered '24 Dec 2020'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 16:07:50

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:52:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Right KNEE BRACE' reason for change: Data Entry Error	(b) (4)	
	Yaman Ahmed (b) (4)	23 Feb 2021 16:08:00
User entered 'knee brace'	(b) (4)	
	Yaman Ahmed (b) (4)	23 Feb 2021 16:07:50
	(b) (4)	

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:52:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 16:07:50

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:52:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:25:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	23 Feb 2021 16:07:50

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:31
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:09:46
User entered '24 Mar 2021'	(b) (4), (b) (6)	29 Apr 2021 13:37:56

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:31
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:09:46
User entered 'ARTHROPLASTY ROBOT-ASSISTED RIGHT TOTAL KNEE'	(b) (4), (b) (6)	29 Apr 2021 13:37:56

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:31
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:09:46
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Apr 2021 13:37:56

US3522513

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:31
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:09:46
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 13:37:56

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:02
User entered 'USA-US131-2021-MRNA-1273-P301000017'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Marcus'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Zervos'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '2799 West Grand Blvd'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Detroit'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '48202'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:45:38
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'US'	(b) (4) System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:45:54
User entered '1'	System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:02
User entered 'USA-US131-2021-MRNA-1273-P301000017'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Marcus'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Zervos'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '2799 West Grand Blvd'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Detroit'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '48202'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:45:38
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'US'	(b) (4) System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:45:54
User entered '1'	System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered '29/Apr/2021 15:37'	(b) (4) System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:08

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)	30 Apr 2021 19:45:38
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:02
User entered 'USA-US131-2021-MRNA-1273-P301000017'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Yes (Y)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'No (N)'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Marcus'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Zervos'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '2799 West Grand Blvd'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered 'Detroit'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:37:05
User entered '48202'	System	29 Apr 2021 19:36:36

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:45:38
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:39
User entered 'US'	(b) (4) System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:45:54
User entered '1'	System	29 Apr 2021 19:37:14

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:19
User entered '30/Apr/2021 12:45'	(b) (4) System	30 Apr 2021 19:45:54

US3522513

Folder: SAE USA-US131-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 May 2021 01:03:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:45:54