

US3522529 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:02:01

All time stamps listed in this document are displayed in GMT

US3522529

**Form: Participant Creation**

**Data signed:** (b) (4) 05 Mar 2021 17:26:34

**Generated On: 10 Jun 2021 08:02:01**

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[Participant ID](#)

US3522529

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

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US3522529

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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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

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US3522529

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3522529

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Date of Informed Consent (*dd MMM yyyy*) 2 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3522529

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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Did the participant meet all eligibility criteria?

Yes

No

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US3522529

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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Were any significant conditions reported?

Yes

No

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US3522529

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Condition	MIGRAINES
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)	

US3522529

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:26:37

Generated On: 10 Jun 2021 08:02:01

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> )	12:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:17
Height ( <i>xxx.x</i> )	65 in
Weight ( <i>xxx.x</i> )	169 lb
BMI ( <i>xxx.x</i> )	28.18187 kg/m <sup>2</sup>
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	ND - Not Done
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)	_____

US3522529

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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Was the physical examination performed?

Yes

No

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Date of examination (*dd MMM yyyy*) \_\_\_\_\_

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

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US3522529

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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*) \_\_\_\_\_

Date of surgery unknown False

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

Date of last menstruation unknown False

US3522529

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 2 SEP 2020

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3522529

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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**Occupational Risk**

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**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

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**Specify** \_\_\_\_\_

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**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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US3522529

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 17:26:36

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

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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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	VISIT1

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US3522529

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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

What was the participant's randomization number? 110955

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

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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Height	ND - Not Done
Weight	ND - Not Done

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US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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)	12:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:17
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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 ( <i>dd MMM yyyy</i> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:14 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 13:14
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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Was the physical examination performed?

Yes

No

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Date of examination (*dd MMM yyyy*) \_\_\_\_\_

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

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US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

Was the pregnancy test performed? Yes   
No

Date of test (*dd MMM yyyy*) \_\_\_\_\_

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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) 12:44 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 12:44

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

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	2 SEP 2020
Collection time ( <i>00:00-23:59</i> )	12:30 (24 HR)
Collection date and time (derived)	2 SEP 2020 12:30

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US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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Collection date ( <i>dd MMM yyyy</i> )	2 SEP 2020		
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:36	2 SEP 2020 12:36
Nasopharyngeal Swab 2	No		

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US3522529

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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Is the participant continuing to the next visit?

Yes

No

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Continuing Flag

1

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 02 SEP 2020 13:11

PC Open Date & Time 02 SEP 2020 13:04

PC Close Date & Time 02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**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 99.5 °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 SEP 2020 16:30  
PC Open Date & Time 02 SEP 2020 16:29  
PC Close Date & Time 03 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 12:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**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 99.1 °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):

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

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

PC Time Stamp 04 SEP 2020 12:01

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 13:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 21:22
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**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 99.1 °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):

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

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

PC Time Stamp 07 SEP 2020 20:02

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 14:51
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

02 SEP 2020 13:12

PC Open Date & Time

02 SEP 2020 13:04

PC Close Date & Time

02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**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 16:32
PC Open Date & Time	02 SEP 2020 16:29
PC Close Date & Time	03 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 2

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	03 SEP 2020 12:02
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 3

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	04 SEP 2020 12:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 4

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	05 SEP 2020 13:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 5

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	06 SEP 2020 21:22
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 6

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

07 SEP 2020 20:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 7

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

08 SEP 2020 14:52

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

No

Yes

PC Time stamp	02 SEP 2020 13:12
PC Open Date & Time	02 SEP 2020 13:04
PC Close Date & Time	02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

No

Yes

---

PC Time stamp	02 SEP 2020 16:33
PC Open Date & Time	02 SEP 2020 16:29
PC Close Date & Time	03 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

---

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

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 12:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 13:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 21:23
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 20:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 14:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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

---

PC Time Stamp 10 SEP 2020 06:05

---

PC Open Date & Time 09 SEP 2020 12:00

---

PC Close Date & Time 10 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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

---

PC Time Stamp 10 SEP 2020 12:00

---

PC Open Date & Time 10 SEP 2020 12:00

---

PC Close Date & Time 11 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**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

---

PC Time Stamp

---

PC Open Date & Time

11 SEP 2020 12:00

---

PC Close Date & Time

12 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None

**HEADACHE**

No interference with activity

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

Any use of prescription pain  
reliever or prevents daily activity

---

PC Time Stamp

12 SEP 2020 12:11

---

PC Open Date & Time

12 SEP 2020 12:00

---

PC Close Date & Time

13 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

10 SEP 2020 06:05

---

PC Open Date & Time

09 SEP 2020 12:00

---

PC Close Date & Time

10 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

10 SEP 2020 12:00

---

PC Open Date & Time

10 SEP 2020 12:00

---

PC Close Date & Time

11 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

12 SEP 2020 12:12

---

PC Open Date & Time

12 SEP 2020 12:00

---

PC Close Date & Time

13 SEP 2020 11:59

---

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 06:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 12:00
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 11
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 12:11
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

---

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

---

Comments EDIARY REVIEWED. PATIENT  
*If Contact Not Made, please provide Comments* REPORTS MILD PAIN AT  
INJECTION SITE, HEADACHES,  
MUSCLE/JOINT ACHES AND  
FATIGUE THAT PEAKED ON  
DAY 3 AND RETURNED ON  
DAYS 6-8. SYMPTOMS  
CONTROLLED WITH 800MG  
OTC IBUPROFEN

---

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 16 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*

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

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 PATIENT CONTACTED, HAD  
WENT TO HOSPITAL FOR  
*If Contact Not Made, please provide Comments* HERNIA AND ADMITTED FOR  
LOW ELECTROLYTES ON  
9/21/2020. PATIENT IS STILL  
ADMITTED CURRENTLY.  
PHYSICIAN CONTACTING

---

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

---

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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 ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	12:22 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:22
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	78 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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 ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	12:55 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:55
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

7 OCT 2020

---

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

---

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 7 OCT 2020

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 12:35

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

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 7 OCT 2020

---

Collection time (*00:00-23:59*) 12:25 (24 HR)

---

Collection date and time (derived) 7 OCT 2020 12:25

---

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Collection date ( <i>dd MMM yyyy</i> )			7 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:30	7 OCT 2020 12:30
Nasopharyngeal Swab 2	No		

---

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**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  
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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 07 OCT 2020 12:55

PC Close Date & Time 07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.6 °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 07 OCT 2020 16:21

PC Open Date & Time 07 OCT 2020 16:20

PC Close Date & Time 08 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 99.7 °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):

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

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

PC Time Stamp 08 OCT 2020 12:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**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 99.0 °F

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

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

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

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

PC Time Stamp 09 OCT 2020 14:57

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.4 °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):

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

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

PC Time Stamp 12 OCT 2020 09:42

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.4 °F

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

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

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

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

PC Time Stamp 12 OCT 2020 20:22

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 OCT 2020 06:01
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

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

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

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

PC Open Date & Time

07 OCT 2020 12:55

PC Close Date & Time

07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**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	07 OCT 2020 16:22
PC Open Date & Time	07 OCT 2020 16:20
PC Close Date & Time	08 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 2

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	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 OCT 2020 14:57
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 OCT 2020 12:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 5

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	12 OCT 2020 09:43
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 6

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

12 OCT 2020 20:22

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 7

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	14 OCT 2020 06:01
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

No

Yes

PC Time stamp

PC Open Date & Time

07 OCT 2020 12:55

PC Close Date & Time

07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

No

Yes

---

PC Time stamp	07 OCT 2020 16:22
PC Open Date & Time	07 OCT 2020 16:20
PC Close Date & Time	08 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

---

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

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 14:58
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 09:43
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 20:23
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**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

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

---

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 06:02
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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

PC Time Stamp 15 OCT 2020 06:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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

---

PC Time Stamp 15 OCT 2020 12:00

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None

**HEADACHE**

No interference with activity

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

Any use of prescription pain  
reliever or prevents daily activity

---

PC Time Stamp 16 OCT 2020 12:06

---

PC Open Date & Time 16 OCT 2020 12:00

---

PC Close Date & Time 17 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

15 OCT 2020 06:40

---

PC Open Date & Time

14 OCT 2020 12:00

---

PC Close Date & Time

15 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

15 OCT 2020 12:00

---

PC Open Date & Time

15 OCT 2020 12:00

---

PC Close Date & Time

16 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

16 OCT 2020 12:06

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

18 OCT 2020 00:00

---

PC Open Date & Time

17 OCT 2020 12:00

---

PC Close Date & Time

18 OCT 2020 11:59

---

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 06:40
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 12:00
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 12:07
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 11
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 00:00
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

---

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

---

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

---

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

---

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

---

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

---

*If Contact Not Made, please provide Comments*

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

---

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

---

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

---

*If Contact Not Made, please provide Comments*

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:05

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

---

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	12:00 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 12:00
Temperature ( <i>xxx.x</i> )	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

5 NOV 2020

---

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

---

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	5 NOV 2020
Collection time ( <i>00:00-23:59</i> )	12:10 (24 HR)
Collection date and time (derived)	5 NOV 2020 12:10

---

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:11:06

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 04 NOV 2020 12:00:47

Patient Cloud Open Date & Time 02 NOV 2020 00:01

Patient Cloud Close Date & Time 06 NOV 2020 23:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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 06:27:55

Patient Cloud Open Date & Time 09 NOV 2020 00:01

Patient Cloud Close Date & Time 13 NOV 2020 23:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 NOV 2020 06:04:12
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 82

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

---

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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	01 DEC 2020 11:34:19
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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	04 DEC 2020 06:19:05
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 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	11 DEC 2020 00:01:30
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 06:10:17
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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 28 DEC 2020 17:59:23

Patient Cloud Open Date & Time 25 DEC 2020 00:01

Patient Cloud Close Date & Time 29 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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	03 JAN 2021 12:00:51
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 08:18:55
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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 15 JAN 2021 07:34:46

Patient Cloud Open Date & Time 15 JAN 2021 00:01

Patient Cloud Close Date & Time 19 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 JAN 2021 10:46:25
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

---

<b>TIMEPOINT</b>	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 FEB 2021 18:26:36
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

---

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 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 FEB 2021 18:01:56
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission

14 FEB 2021 12:03:29

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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 23 FEB 2021 15:08:27

Patient Cloud Open Date & Time 19 FEB 2021 00:01

Patient Cloud Close Date & Time 23 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 11:59:29
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 <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	09 MAR 2021 11:59:24
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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	16 MAR 2021 12:05:31
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 12:25:03
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 <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	26 MAR 2021 07:05:27
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 18:08:00
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 <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	11 APR 2021 12:05:24
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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 19 APR 2021 17:59:38

Patient Cloud Open Date & Time 16 APR 2021 00:01

Patient Cloud Close Date & Time 20 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 12:03:25
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 243

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 250

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 264

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAY 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 292

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 320

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 327

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 AUG 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 341

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 SEP 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 411

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[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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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 425

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[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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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 460

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 488

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 516

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 FEB 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 523

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 FEB 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 530

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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01 MAR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#) 05 APR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 600

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 APR 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 614

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAY 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAY 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 670

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 698

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3522529

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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

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 AUG 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 712

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 726

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 733

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 740

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

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US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**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°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

---

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

---

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 782

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

---

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

---

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 NOV 2022 23:59

---

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

---

US3522529

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:02:01

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
Yes	Yes	02 MAR 2021 11:59:53

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 2 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

---

*If Contact Not Made, please provide Comments*

US3522529

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 7 JAN 2021

---

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

---

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

*If Contact Not Made, please provide Comments*

US3522529

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 FEB 2021

---

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

---

Comments LEFT VM

---

*If Contact Not Made, please provide Comments*

---

US3522529

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 15:28:33

Generated On: 10 Jun 2021 08:02:01

---

Was Contact Attempted? Yes   
No

---

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

*If Contact Not Made, please provide Comments*

US3522529

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:28:33

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522529

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 26 MAR 2021

---

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

---

Folder OID VISIT4

---

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

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) \_\_\_\_\_

US3522529

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

---

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.*

---

US3522529

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	26 MAR 2021
Collection time ( <i>00:00-23:59</i> )	08:12 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:12

---

US3522529

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3522529**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:02:01**

---

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* \_\_\_\_\_

---

US3522529

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Date of Contact	16 NOV 2020
Time of Contact	15:30
Date and Time of Contact (derived)	16 NOV 2020 15:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

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

---

Date 15 NOV 2020

---

Assessment Not Done False

---

O2 Saturation ND - Not Done

---

O2 Saturation Units %

---

Temperature ND - Not Done

---

Chills

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

---

Cough

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

---

Shortness of Breath

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

---

Difficulty Breathing

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

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

343 of 2758

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Symptom Day

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

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

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

---

Date	16 NOV 2020
------	-------------

---

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

---

O2 Saturation	97 %
---------------	------

---

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

---

Temperature	98.8 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

347 of 2758

EAB) (1725)

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Symptom Day

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

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

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

---

Date 17 NOV 2020

---

Assessment Not Done False

---

O2 Saturation 98 %

---

O2 Saturation Units %

---

Temperature 97.8 F

---

Chills

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

---

Cough

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

---

Shortness of Breath

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

---

Difficulty Breathing

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

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Symptom Day

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

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

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

---

Date	18 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	98 F
-------------	------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

355 of 2758

EAB) (1725)

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

Symptom Day

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

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

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

---

Date	19 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	97.8 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

359 of 2758

EAB) (1725)

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Date of Visit 16 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes   
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes   
No

Date of Test 16 NOV 2020

Type of Test Performed Nasopharyngeal Swab   
Nasal Swab   
Saliva Test   
Other

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes   
No

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes   
No

COVID-19 Positive (CSA Programming Field Only) 0

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 NOV 2020
Day 5	Yes	20 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 NOV 2020

---

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

---

Folder OID SICKD1

---

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 16 NOV 2020

Time of assessment (00:00-23:59) 15:40 (24 HR)

Vital Signs Date and Time (derived) 16 NOV 2020 15:40

Height (xxx.x) 65 in

Weight (xxx.x) 175 lb

Temperature (xxx.x) 98.8 F

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) 97 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 116 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 80 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

16 NOV 2020

---

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

---

US3522529

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

16 NOV 2020

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) \_\_\_\_\_

---

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

---

Folder OID SICKD28

---

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

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) \_\_\_\_\_

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

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.*

---

US3522529

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection \_\_\_\_\_

---

---

US3522529

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 26 MAR 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3522529

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 11:49:06

Generated On: 10 Jun 2021 08:02:01

Date of updated informed consent (*dd MMM yyyy*) 26 MAR 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*) 29 DEC 2020

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 \_\_\_\_\_

US3522529

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	26 MAR 2021
Collection time ( <i>00:00-23:59</i> )	08:12 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:12

---

US3522529

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 11:49:05

Generated On: 10 Jun 2021 08:02:01

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	26 MAR 2021
Collection time ( <i>00:00 - 23:59</i> )	08:08
Collection Date and Time (derived)	26 MAR 2021 08:08

---

US3522529

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:26:35

Generated On: 10 Jun 2021 08:02:01

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID USA-US131-2020-MRNA-1273-P30  
1000006

Adverse event HERNIATED DISC

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 21 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 21 SEP 2020

Hospital Discharge Date (dd MMM yyyy) 23 SEP 2020

Admitted to ICU? Yes   
No   
Unknown

PRODUCTION RELEASE (v12.003  
EAB) (1725)

377 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

---

Number of Days in ICU \_\_\_\_\_

---

Persistent or significant disability or incapacity False

---

Congenital anomaly or birth defect False

---

Other medically important event False

---

Relationship to investigational product Not Related   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

---

Narrative \_\_\_\_\_

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

---

WENT TO HOSPITAL 9/21 AFTER  
PACKING AND MOVING  
RECENTLY AND DEVELOPING  
SEVERE LOW BACK PAIN. WAS  
ADMITTED DUE TO  
ELECTROLYTE  
ABNORMALITIES IN LAB WITH  
CALCIUM 5.1, K + 3.1, MG 1.1.  
COVID 19 NP SWAB WAS GIVEN  
ON INTAKE AND RESULTS  
WERE NEGATIVE. NO  
NAUSEA/VOMITING/DIARRHEA.  
WAS GIVEN IV CORRECTION OF  
MAGNESIUM/POTASSIUM/CALC  
IUM. SENT HOME IN LATE  
AFTERNOON ON SEP 23, 2020  
WITH PREDNISONE DOSE,  
ULTRAM AND ROBAXIN FOR  
PAIN. (SEE CONCOM. MEDS).  
FEELING BETTER, AND WANTS  
TO STILL PARTICIPATE IN  
TRIAL. DURING ADMITTANCE,  
ENDOCRINOLOGIST  
DETERMINED THAT THE  
ELECTROLYTE IMBALANCE WAS  
IN ACTUALITY A LAB ERROR  
DUE TO RAPID  
NORMALIZATION OF ALBUMIN  
LEVELS IN 12 HOURS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	HEADACHE MODERATE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

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

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID

Adverse event

MUSCLE ACHES  
ALL OVER BODY DAY 8

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

14 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

PRODUCTION RELEASE (v12.003

382 of 2758

EAB) (1725)

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT STATES SHE IS STILL EXPERIENCING MILD MUSCLE ACHES ON DAY 8 AFTER INJECTION.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

383 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

385 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	NASAL CONGESTION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

387 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	SORE THROAT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

389 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	ELECTROLYTE IMBALANCE
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)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related   
Related   
Not Applicable

Relationship to Study Procedure Not Related   
Related   
Not Applicable

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative \_\_\_\_\_

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 1

Admitted to ICU Derived (CSA Programming Field Only) \_\_\_\_\_

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID

Adverse event FATIGUE - MILD

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 08 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related   
Related   
Not Applicable

Relationship to Study Procedure Not Related   
Related   
Not Applicable

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

Other action taken (check all that apply)  
None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative \_\_\_\_\_

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) \_\_\_\_\_

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	FATIGUE - MILD
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

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

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	HEADACHE MILD
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

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

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

AEID	
Adverse event	HEADACHE - MODERATE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

398 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 13:41:23

Generated On: 10 Jun 2021 08:02:01

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

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:26:35

Generated On: 10 Jun 2021 08:02:01

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

Yes

No

---

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

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication MIGRAINES/HEADACHES/  
GENERALIZED PAIN

Dose per administration 800

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

401 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

	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) \_\_\_\_\_

---

Start date completely unknown True

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication ZOMIG-ZMT

Prophylaxis Yes   
No

Indication MIGRAINES

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

403 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes   
No

Indication PRESUMED ELECTROLYTE  
IMBALANCE

Dose per administration 2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

405 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 21 SEP 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes   
No

Indication PRESUMED ELECTROLYTE  
IMBALANCE

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

407 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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 checked="" type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy)	21 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)	22 SEP 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"/>

---

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes   
No

Indication PRESUMED ELECTROLYTE  
IMBALANCE

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

409 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 21 SEP 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication PREDNISONE

Prophylaxis Yes   
No

Indication HERNIATED DISC

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

411 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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*) 23 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 27 SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication TRAMADOL

Prophylaxis Yes   
No

Indication HERNIATED DISC

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

413 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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*) 23 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 25 SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 4

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication ROBAXIN

Prophylaxis Yes   
No

Indication HERNIATED DISC

Dose per administration UNKNOWN

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)

415 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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*) 23 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 25 SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication MOTRIN

Prophylaxis Yes   
No

Indication HEADACHE, MUSCLE ACHE,  
JOINT PAIN

Dose per administration 600

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

417 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

	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) 07 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 12 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication KDUR

Prophylaxis Yes   
No

Indication PRESUMED ELECTROLYTE  
IMBALANCE

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

419 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

	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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 21 SEP 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication FLU VACCINE

Prophylaxis Yes   
No

Indication INFLUENZA

Dose per administration UNK

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNK

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)

421 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 4 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 4 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication BOTOX

Prophylaxis Yes   
No

Indication MIGRAINES

Dose per administration 200

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

EVERY THREE MONTHS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

423 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

---

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 JAN 2019

---

Start date completely unknown \_\_\_\_\_ False

---

Ongoing? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) \_\_\_\_\_ 802

\_\_\_\_\_ 803

\_\_\_\_\_ 804

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

Name of Medication ZANAFLEX

Prophylaxis Yes   
No

Indication MIGRAINES

Dose per administration 4

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)

425 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 11:59:32

Generated On: 10 Jun 2021 08:02:01

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*) 10 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	LAB WORK INCLUDING PHLEBOTOMY.	Diagnostic	

US3522529

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:02:01

---

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

---

US3522529

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:02:01

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

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 21:48
<b>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.</b>	<input checked="" type="checkbox"/> True

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/SEP/2020 14:45
<b>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.</b>	<input checked="" type="checkbox"/> True

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/OCT/2020 13:01
<b>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.</b>	True

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/OCT/2020 18:40
<b>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.</b>	True

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 17:26:36

Generated On: 10 Jun 2021 08:02:01

SAEID	USA-US131-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/DEC/2020 13:38
<b>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.</b>	<input checked="" type="checkbox"/> True

Audit

US3522529 (Prod: Henry Ford Health System)

US3522529

Form: Participant Creation

Generated On: 10 Jun 2021 08:02:01

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 23:46:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'US3522529'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:28

US3522529

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:12
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:30

US3522529

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'SCRN'	System	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:32

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '44'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'YEARS'	System	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered '44'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered 'Female (F)'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:01

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:42
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'Sep 2020'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered '2020'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:30

US3522529

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered '1'	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:02:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	16 Sep 2020 18:22:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:09:33

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:24:40
Data point term sent to Coder	System	16 Sep 2020 18:23:12
User entered 'Migraines'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User entered '1'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:41
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered '12:17'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered '2 Sep 2020 12:17'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered '65' in	(b) (4), (b) (6)	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered '169' lb	(b) (4), (b) (6)	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered '28.18187'	System	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'kg/m2'	System	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'bpm'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'breaths/min'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'mmHg'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered 'mmHg'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19

US3522529

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:09:39

US3522529

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:20:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:39

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	08 Sep 2020 18:43:56
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	02 Sep 2020 16:09:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	08 Sep 2020 18:43:56
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:02:01

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:01
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	08 Sep 2020 18:43:56
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered 'Urine (URINE)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:10
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User entered empty.	System	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

**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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

**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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

**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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

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 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:29:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:19
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:24
User entered '02 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 17:54:43
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[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 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'VISIT1'	System	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered '110955'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:21:30
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 17:54:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:54:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:54:16

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '12:17'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '2 Sep 2020 12:17'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '98.8' F	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered 'Temporal'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '80'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'bpm'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '16'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'breaths/min'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '111'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'mmHg'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '73'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'mmHg'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:17:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:17:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 16:19:12
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '13:14' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '2 Sep 2020 13:14'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

(

**US3522529**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'bpm'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'breaths/min'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'mmHg'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:22:02
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'mmHg'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:07:20
User closed query 'Per guidelines, since screening visit and physical exam occurred on the same day, please change response to NO and leave date field blank.' (Site from CRA).	(b) (4), (b) (6)	27 Feb 2021 15:33:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
Query 'Per guidelines, since screening visit and physical exam occurred on the same day, please change response to NO and leave date field blank.' answered with 'updated' (Site from CRA).	Sharon Mathys (b) (4)	11 Dec 2020 14:51:30
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Dec 2020 14:51:22
User opened query 'Per guidelines, since screening visit and physical exam occurred on the same day, please change response to NO and leave date field blank.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 00:23:06
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 00:22:09
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:22:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:11:38

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:07:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 14:51:22
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 00:22:11
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:22:05
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:11:38

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:06:31
User entered 'No (N)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 17:51:27
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'correct per ccg' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 13:48:46
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:23:57
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:11
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered empty.	System	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered '12:44'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '2 Sep 2020 12:44'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:23:18
User entered 'ONCE'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:22
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:22
User entered '12:30'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '2 Sep 2020 12:30'	System	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:25
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:25
User entered '12:36'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '2 Sep 2020 12:36'	System	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:25
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:31:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 14:31:37
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:31:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 16:42:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:25
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered empty.	System	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:46:02

US3522529

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '1'	System	02 Sep 2020 16:46:02

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:10:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad' User entered 'Yes (Y)'	System	02 Sep 2020 17:11:07
	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:10:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad' User entered '98.1'	System	02 Sep 2020 17:11:07
	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad'	System	02 Sep 2020 17:11:07
User entered 'No (N)'	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad' User entered '02 Sep 2020 13:11'	System	02 Sep 2020 17:11:07
	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:29:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010' User entered 'Yes (Y)'	System	02 Sep 2020 20:30:48
	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010' User entered '99.5'	System	02 Sep 2020 20:30:48
	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010'	System	02 Sep 2020 20:30:48
User entered 'No (N)'	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010' User entered '02 Sep 2020 16:30'	System	02 Sep 2020 20:30:48
	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered 'Yes (Y)'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered '98.7'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered 'No (N)'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:00:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed' User entered 'Yes (Y)'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed' User entered '99.1'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	System	04 Sep 2020 16:03:33
User entered 'Yes (Y)'	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'from safety call day 8, used ibuprophen for pain see line 1 in concom. meds' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:31:42
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.'	Sharon Mathys (b) (4)	23 Sep 2020 16:51:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	(b) (4)	
User entered '1'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed' User entered '0'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed' User entered '04 Sep 2020 12:01'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:30:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered 'Yes (Y)'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:31:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102' User entered '99.1'	System	05 Sep 2020 17:32:07
	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:31:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered 'No (N)'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafae' User entered 'Yes (Y)'	System	07 Sep 2020 01:22:30
	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:23', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafae' User entered '98.9'	System	07 Sep 2020 01:22:30
	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafae'	System	07 Sep 2020 01:22:30
User entered 'No (N)'	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafae' User entered '06 Sep 2020 21:22'	System	07 Sep 2020 01:22:30
	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:00:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3' User entered '99.1'	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'from safety call day 8, used ibuprophen for pain see line 1 in concom. meds' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:31:53
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.'	Sharon Mathys (b) (4)	23 Sep 2020 16:51:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	(b) (4)	
User entered '1'	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3' User entered '0'	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered '07 Sep 2020 20:02'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered 'Yes (Y)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered '98.8'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered 'No (N)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered '08 Sep 2020 14:51'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a'	System	02 Sep 2020 17:12:26
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered 'No (N)'	System	02 Sep 2020 17:12:26
	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered 'No (N)'	System	02 Sep 2020 17:12:26
	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:21', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a'	System	02 Sep 2020 17:12:26
User entered 'None (1)'	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered '02 Sep 2020 13:12'	System	02 Sep 2020 17:12:26
	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'No (N)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'No (N)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'None (1)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'No (N)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'No (N)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'None (1)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6' User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:03:53
	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd'	System	04 Sep 2020 16:04:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered 'No (N)'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered 'No (N)'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered 'None (1)'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'None (1)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:10', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'No (N)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:12', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'No (N)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'None (1)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4' User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:24
	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'None (1)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b' User entered 'No (N)'	System	07 Sep 2020 01:22:49
	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'No (N)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'None (1)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b' User entered '06 Sep 2020 21:22'	System	07 Sep 2020 01:22:49
	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'None (1)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'None (1)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152' User entered '07 Sep 2020 20:02'	System	08 Sep 2020 00:02:51
	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'None (1)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'No (N)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'No (N)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'None (1)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered '08 Sep 2020 14:52'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'No interference with activity (1)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'No (N)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered '02 Sep 2020 13:12'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e'	System	02 Sep 2020 20:33:20
User entered 'No interference with activity (1)'	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'No (N)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered '02 Sep 2020 16:33'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'None (0)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'None (0)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'None (0)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'None (0)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'No (N)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:03:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered '03 Sep 2020 12:03'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'None (0)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'No interference with activity (1)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered 'No (N)'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e' User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:42
	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'No (N)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767' User entered 'None (0)'	System	07 Sep 2020 01:23:07
	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767' User entered 'None (0)'	System	07 Sep 2020 01:23:07
	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:23:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'No (N)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:23:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered '06 Sep 2020 21:23'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'Some interference with activity (2)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'No (N)'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered '07 Sep 2020 20:03'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:10', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:16', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered 'None (0)'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered 'None (0)'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered 'None (0)'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered 'None (0)'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered 'No (N)'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6' User entered '08 Sep 2020 14:52'	System	08 Sep 2020 18:52:29
	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 00:03:21
User entered 'Day 8'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c5e5fade-8cf3-4201-8452-9e1c5f09205d'	System	10 Sep 2020 10:05:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c5e5fade-8cf3-4201-8452-9e1c5f09205d' User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:37
	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fa357290-0937-449c-ad0e-0d84ebfb44de' User entered 'No interference with activity (1)'	System	10 Sep 2020 16:00:47
	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fa357290-0937-449c-ad0e-0d84ebfb44de' User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:00:47
	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 10:05:37
User entered 'Day 10'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 16:00:47
User entered 'Day 11'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e191cd57-23a8-4bc2-94be-2b257f0ef8f9'	System	12 Sep 2020 16:16:45
User entered 'None (0)'	System	12 Sep 2020 16:16:45

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e191cd57-23a8-4bc2-94be-2b257f0ef8f9'	System	12 Sep 2020 16:16:45
User entered '12 Sep 2020 12:11'	System	12 Sep 2020 16:16:45

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 00:03:21
User entered 'Day 8'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '57724233-6a8e-4787-bc66-49de60b46f29'	System	10 Sep 2020 10:05:45
User entered 'No interference with activity (1)'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '57724233-6a8e-4787-bc66-49de60b46f29' User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:45
	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ddaf3dda-0538-49f4-ae05-04aec01823fe' User entered 'No interference with activity (1)'	System	10 Sep 2020 16:01:17
	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ddaf3dda-0538-49f4-ae05-04aec01823fe' User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:01:17
	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 10:05:45
User entered 'Day 10'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 16:01:17
User entered 'Day 11'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2633ffbe-fff5-4433-9624-7052d175e440' User entered 'None (0)'	System	12 Sep 2020 16:16:50
	System	12 Sep 2020 16:16:50

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:12:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2633ffbe-fff5-4433-9624-7052d175e440' User entered '12 Sep 2020 12:12'	System	12 Sep 2020 16:16:50
	System	12 Sep 2020 16:16:50

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 00:02:37
User entered 'Day 8'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b699eac5-bd02-4a83-9443-bff29203a65b' User entered 'No (N)'	System	10 Sep 2020 10:05:56
	System	10 Sep 2020 10:05:56

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b699eac5-bd02-4a83-9443-bff29203a65b' User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:56
	System	10 Sep 2020 10:05:56

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '137fc4a1-9bfe-4f27-876c-c70e9cdc5748' User entered 'No (N)'	System	10 Sep 2020 16:01:41
	System	10 Sep 2020 16:01:41

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '137fc4a1-9bfe-4f27-876c-c70e9cdc5748' User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:01:41
	System	10 Sep 2020 16:01:41

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 10:05:37
User entered 'Day 10'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	10 Sep 2020 16:00:47
User entered 'Day 11'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ce0d7c4f-f29a-44bc-b8f6-58e7af426f2f' User entered 'No (N)'	System	12 Sep 2020 16:16:48
	System	12 Sep 2020 16:16:48

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ce0d7c4f-f29a-44bc-b8f6-58e7af426f2f' User entered '12 Sep 2020 12:11'	System	12 Sep 2020 16:16:48
	System	12 Sep 2020 16:16:48

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:00:47

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:04
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 05:04:25
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Contact attempted twice prior to patient returning call. ' (Site from System).	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:06:13
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 13:05:31
User entered '15 Sep 2020' reason for change: New Information	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:05:31
User entered '10 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Sep 2020 22:25:40
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:04
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:05:31
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:04
User entered 'EDIARY REVIEWED. PATIENT REPORTS MILD PAIN AT INJECTION SITE, HEADACHES, MUSCLE/JOINT ACHES AND FATIGUE THAT PEAKED ON DAY 3 AND RETURNED ON DAYS 6-8. SYMPTOMS CONTROLLED WITH 800MG OTC IBUPROFEN' reason for change: New Information	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:06:47
User entered 'eDiary reviewed. Patient reports mild pain at injection site, headaches, muscle/joint aches and fatigue that peaked on day 3 and returned mildly on days 6-8. Symptoms controlled with 800mg OTC ibuprofen PRN and no medical intervention.' (non-conformant).	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:05:31
User entered '1ST ATTEMPT ON 09 SEP 2020; SECOND ATTEMPT 10 SEP 2020, left a voicemail' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Sep 2020 22:26:20
User entered '1st attempt on 09 Sep 2020; second attempt 10 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Sep 2020 22:25:40
User entered 'Voicemail full'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:08
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:06:53

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '1'	System	15 Sep 2020 13:06:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:11
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:11
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)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:24:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:32:57

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '1'	System	16 Sep 2020 18:32:57

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:14:37
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:14:37
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '23 Sep 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:14:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Contact Made (CONTACT MADE)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:14:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Patient contacted, had went to hospital for hernia and admitted for low electrolytes on 9/21/2020. Patient is still admitted currently. physician contacting'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:15:32
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:41:41

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:06
User entered '1'	System	07 Oct 2020 16:41:41

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:32
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:32
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:32
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'VISIT2'	System	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '12:22'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '7 Oct 2020 12:22'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '78'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'bpm'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'breaths/min'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '118'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '78'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User closed query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4)	
Query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	Sharon Mathys (b) (4)	20 Oct 2020 14:13:12
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:49:18
User entered '12:55'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '7 Oct 2020 12:55'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '97.5' F reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	20 Oct 2020 18:27:04
User entered '99.5' F	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '76'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'bpm'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '18'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'breaths/min'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '120'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:16:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '77'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:10

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:10

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:18:21
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:02:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered empty.	System	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '12:35'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '7 Oct 2020 12:35'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:43
User entered 'ONCE'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:47
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:47
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:47
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '12:25'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3522529**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '7 Oct 2020 12:25'	System	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '12:30'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:06

**US3522529**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '7 Oct 2020 12:30'	System	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered empty.	System	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:26:03
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:47:13

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	07 Oct 2020 16:47:13

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered 'Yes (Y)'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered '98.6'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered 'Yes (Y)'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'patient took 600mg Motrin PO, per conmed line 9 ' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:30:54
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).	Alandra White (b) (4)	05 Nov 2020 20:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	(b) (4)	
User entered '1'	System	07 Oct 2020 20:21:09
	System	07 Oct 2020 20:21:09
	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered '0'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062' User entered '07 Oct 2020 16:21'	System	07 Oct 2020 20:21:09
	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:13', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8' User entered 'Yes (Y)'	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8' User entered '99.7'	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered 'Yes (Y)'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:31:07
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).	Alandra White (b) (4)	05 Nov 2020 20:00:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	(b) (4)	
User entered '1'	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered '0'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:56:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered 'Yes (Y)'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16' User entered '99.0'	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered 'Yes (Y)'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:31:22
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).	Alandra White (b) (4)	05 Nov 2020 20:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	(b) (4)	
User entered '1'	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16' User entered '0'	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16' User entered '09 Oct 2020 14:57'	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:01:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37' User entered 'Yes (Y)'	System	10 Oct 2020 16:02:22
	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:13', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37' User entered '98.6'	System	10 Oct 2020 16:02:22
	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37'	System	10 Oct 2020 16:02:22
User entered 'No (N)'	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:22
	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9' User entered 'Yes (Y)'	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9' User entered '98.4'	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	System	12 Oct 2020 13:42:59
User entered 'Yes (Y)'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:32:07
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).	Alandra White (b) (4)	05 Nov 2020 20:00:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	(b) (4)	
User entered '1'	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	System	12 Oct 2020 13:42:59
User entered '0'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9' User entered '12 Oct 2020 09:42'	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f' User entered 'Yes (Y)'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:15', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f' User entered '98.4'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f' User entered 'Yes (Y)'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:32:20
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).	Alandra White (b) (4)	05 Nov 2020 20:00:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	(b) (4)	
User entered '1'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f' User entered '0'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f' User entered '12 Oct 2020 20:22'	System	13 Oct 2020 00:22:32
	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered 'Yes (Y)'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered '99.1'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered 'No (N)'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered '14 Oct 2020 06:01'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc' User entered 'No (N)'	System	07 Oct 2020 20:22:37
	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc' User entered 'No (N)'	System	07 Oct 2020 20:22:37
	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc' User entered 'None (1)'	System	07 Oct 2020 20:22:37
	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc' User entered '07 Oct 2020 16:22'	System	07 Oct 2020 20:22:37
	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265' User entered 'No (N)'	System	08 Oct 2020 16:02:56
	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265' User entered 'No (N)'	System	08 Oct 2020 16:02:56
	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 16:02:56
	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'No (N)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'No (N)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'None (1)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e' User entered '09 Oct 2020 14:57'	System	09 Oct 2020 18:57:40
	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4' User entered 'None (1)'	System	10 Oct 2020 16:02:39
	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4' User entered 'No (N)'	System	10 Oct 2020 16:02:39
	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered 'No (N)'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4' User entered 'None (1)'	System	10 Oct 2020 16:02:39
	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:39
	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'None (1)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'No (N)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'No (N)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'None (1)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876' User entered '12 Oct 2020 09:43'	System	12 Oct 2020 13:43:10
	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'None (1)'	System	13 Oct 2020 00:22:43
	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'No (N)'	System	13 Oct 2020 00:22:43
	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'No (N)'	System	13 Oct 2020 00:22:43
	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'None (1)'	System	13 Oct 2020 00:22:43
	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered '12 Oct 2020 20:22'	System	13 Oct 2020 00:22:43
	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'None (1)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'No (N)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'No (N)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'None (1)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578' User entered '14 Oct 2020 06:01'	System	14 Oct 2020 10:02:00
	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'No interference with activity (1)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'No interference with activity (1)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'No (N)'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered '07 Oct 2020 16:22'	System	07 Oct 2020 20:23:03
	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:16', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33
	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered 'None (0)'	System	08 Oct 2020 16:03:33
	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered 'None (0)'	System	08 Oct 2020 16:03:33
	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered 'No (N)'	System	08 Oct 2020 16:03:33
	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 16:03:33
	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'None (0)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'No interference with activity (1)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88' User entered 'None (0)'	System	09 Oct 2020 18:58:07
	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88' User entered 'None (0)'	System	09 Oct 2020 18:58:07
	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:58', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'No (N)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:58:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88' User entered '09 Oct 2020 14:58'	System	09 Oct 2020 18:58:07
	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'None (0)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered 'No (N)'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db'	System	12 Oct 2020 13:43:48
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'No interference with activity (1)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'No interference with activity (1)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'No (N)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered '12 Oct 2020 09:43'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0' User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10
	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0' User entered 'None (0)'	System	13 Oct 2020 00:23:10
	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0' User entered 'None (0)'	System	13 Oct 2020 00:23:10
	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No (N)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0' User entered '12 Oct 2020 20:23'	System	13 Oct 2020 00:23:10
	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'No interference with activity (1)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'No interference with activity (1)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'No (N)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered '14 Oct 2020 06:02'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	13 Oct 2020 00:23:10
User entered 'Day 8'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fabdf3d5-c77d-450b-ad60-08036d7e67c9'	System	15 Oct 2020 10:40:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fabdf3d5-c77d-450b-ad60-08036d7e67c9' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:39
	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:23:10

**US3522529**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 08:02:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b14c58b5-7057-405f-b6a3-2737bc96b58d'	System	15 Oct 2020 16:00:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b14c58b5-7057-405f-b6a3-2737bc96b58d' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:00:52
	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	15 Oct 2020 10:40:39
User entered 'Day 10'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1a7b128a-b5b9-4b3e-8621-291f5546544b' User entered 'None (0)'	System	16 Oct 2020 16:06:55
	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1a7b128a-b5b9-4b3e-8621-291f5546544b' User entered '16 Oct 2020 12:06'	System	16 Oct 2020 16:06:55
	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	13 Oct 2020 00:23:10
User entered 'Day 8'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e2fe5970-42fc-4fb4-9ea5-ff826cd3b3cc' User entered 'No interference with activity (1)'	System	15 Oct 2020 10:40:47
	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e2fe5970-42fc-4fb4-9ea5-ff826cd3b3cc' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:47
	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c38fc664-66d0-4788-818e-0ae3a36aa69d'	System	15 Oct 2020 16:01:14
User entered 'No interference with activity (1)'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c38fc664-66d0-4788-818e-0ae3a36aa69d' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:01:14
	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	15 Oct 2020 10:40:47
User entered 'Day 10'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '75cca891-999a-46a1-9651-8856f38508b9'	System	16 Oct 2020 16:07:05
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:07:05

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '75cca891-999a-46a1-9651-8856f38508b9' User entered '16 Oct 2020 12:06'	System	16 Oct 2020 16:07:05
	System	16 Oct 2020 16:07:05

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	15 Oct 2020 16:01:14
User entered 'Day 11'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1c380e7a-105e-4f7b-8c36-587bb807cd23' User entered 'None (0)'	System	18 Oct 2020 04:00:06
	System	18 Oct 2020 04:00:06

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1c380e7a-105e-4f7b-8c36-587bb807cd23' User entered '18 Oct 2020 00:00'	System	18 Oct 2020 04:00:06
	System	18 Oct 2020 04:00:06

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	13 Oct 2020 00:22:32
User entered 'Day 8'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fe31633f-9d45-402e-ae12-c919e5355ce0'	System	15 Oct 2020 10:40:53
User entered 'No (N)'	System	15 Oct 2020 10:40:53

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fe31633f-9d45-402e-ae12-c919e5355ce0' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:53
	System	15 Oct 2020 10:40:53

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7a00be97-d7a3-464f-af85-a62b7c42a7c0' User entered 'No (N)'	System	15 Oct 2020 16:01:15
	System	15 Oct 2020 16:01:15

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7a00be97-d7a3-464f-af85-a62b7c42a7c0' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:01:15
	System	15 Oct 2020 16:01:15

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	15 Oct 2020 10:40:39
User entered 'Day 10'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:07:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7b6cf210-a966-4112-bcc2-cfd3f64311de' User entered 'No (N)'	System	16 Oct 2020 16:07:11
	System	16 Oct 2020 16:07:11

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:07:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7b6cf210-a966-4112-bcc2-cfd3f64311de' User entered '16 Oct 2020 12:07'	System	16 Oct 2020 16:07:11
	System	16 Oct 2020 16:07:11

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
Data entry locked.	System	15 Oct 2020 16:00:52
User entered 'Day 11'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '65ad3613-5971-42ad-ba42-37b80b15b43e'	System	18 Oct 2020 04:00:13
User entered 'No (N)'	System	18 Oct 2020 04:00:13
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '65ad3613-5971-42ad-ba42-37b80b15b43e'	System	18 Oct 2020 04:00:13
User entered '18 Oct 2020 00:00'	System	18 Oct 2020 04:00:13
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 08:02:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:00:52

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:36
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
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) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:29:40
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:25:10

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	14 Oct 2020 14:25:10

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '21 Oct 2020'	(b) (4) Yaman Ahmed (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
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'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:32
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:36

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	21 Oct 2020 17:16:36

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	28 Oct 2020 18:58:26
	(b) (4)	

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '28 Oct 2020'	(b) (4) Yaman Ahmed (b) (4)	28 Oct 2020 18:58:26
	(b) (4)	

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
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'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:32

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	28 Oct 2020 18:58:32

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '5 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:30:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Clinic (Clinic)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'VISIT3'	System	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'k' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 03:40:16
User entered '05 Nov 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	12 Nov 2020 14:02:33
	(b) (4)	
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	Sharon Mathys (b) (4)	12 Nov 2020 14:02:29
User entered '5 Nov 2020'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 09:13:33
	Alayna Wilder (b) (4)	05 Nov 2020 17:29:01
	(b) (4)	

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '12:00'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '05 Nov 2020 12:00'	System	12 Nov 2020 14:02:29
User entered '5 Nov 2020 12:00'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '97.1' F	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Other (Other)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'temporal'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '80'	(b) (4) Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'bpm'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '18'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'breaths/min'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '125'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '62'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered 'mmHg'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:14

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered '5 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:14

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:59
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '5 Nov 2020'	(b) (4) Alayna Wilder (b) (4)	05 Nov 2020 17:29:26
	(b) (4)	

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered '12:10'	(b) (4) Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '5 Nov 2020 12:10'	System	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:09
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:31

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	05 Nov 2020 17:29:31

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 64'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650'	System	04 Nov 2020 17:01:57
User entered 'No (N)'	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650'	System	04 Nov 2020 17:01:57
User entered 'No (N)'	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650' User entered '04 Nov 2020 12:00:47'	System	04 Nov 2020 17:01:57
	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 71'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957'	System	09 Nov 2020 11:27:59
User entered 'No (N)'	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957'	System	09 Nov 2020 11:27:59
User entered 'No (N)'	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957' User entered '09 Nov 2020 06:27:55'	System	09 Nov 2020 11:27:59
	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 78'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'Yes (Y)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'No (N)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'Yes (Y)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '1'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '1'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '1'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:04:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'No (N)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:04:12', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '16 Nov 2020 06:04:12'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:32:36
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-01T11:34:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '21c65396-46bb-4f5e-bf63-0df19038b036'	System	01 Dec 2020 16:34:23
User entered 'No (N)'	System	01 Dec 2020 16:34:23

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-01T11:34:16', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '21c65396-46bb-4f5e-bf63-0df19038b036' User entered 'No (N)'	System	01 Dec 2020 16:34:23
	System	01 Dec 2020 16:34:23

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-01T11:34:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '21c65396-46bb-4f5e-bf63-0df19038b036' User entered '01 Dec 2020 11:34:19'	System	01 Dec 2020 16:34:23
	System	01 Dec 2020 16:34:23

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-04T06:18:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f825a32d-344c-4449-b86e-144ab02edb53'	System	04 Dec 2020 11:19:10
User entered 'No (N)'	System	04 Dec 2020 11:19:10

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-04T06:19:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f825a32d-344c-4449-b86e-144ab02edb53'	System	04 Dec 2020 11:19:10
User entered 'No (N)'	System	04 Dec 2020 11:19:10

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-04T06:19:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f825a32d-344c-4449-b86e-144ab02edb53' User entered '04 Dec 2020 06:19:05'	System	04 Dec 2020 11:19:10
	System	04 Dec 2020 11:19:10

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-11T00:01:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7e008b0e-848d-4cdd-b144-bc6cca47a63'	System	11 Dec 2020 05:02:27
User entered 'No (N)'	System	11 Dec 2020 05:02:27

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-11T00:01:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7e008b0e-848d-4cdd-b144-bc6cca47a63'	System	11 Dec 2020 05:02:27
User entered 'No (N)'	System	11 Dec 2020 05:02:27

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-11T00:01:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7e008b0e-848d-4cdd-b144-bc6ccca47a63' User entered '11 Dec 2020 00:01:30'	System	11 Dec 2020 05:02:27
	System	11 Dec 2020 05:02:27

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-18T06:10:10', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '62993b52-6a02-4b53-be52-eddef0f3be5a'	System	18 Dec 2020 11:10:19
User entered 'No (N)'	System	18 Dec 2020 11:10:19

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-18T06:10:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '62993b52-6a02-4b53-be52-eddef0f3be5a' User entered 'No (N)'	System	18 Dec 2020 11:10:19
	System	18 Dec 2020 11:10:19

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-18T06:10:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '62993b52-6a02-4b53-be52-eddef0f3be5a' User entered '18 Dec 2020 06:10:17'	System	18 Dec 2020 11:10:19
	System	18 Dec 2020 11:10:19

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-28T17:59:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a76fad0c-d9ee-4314-a9d6-de881cb417cb' User entered 'No (N)'	System	28 Dec 2020 22:59:26
	System	28 Dec 2020 22:59:26

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-28T17:59:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a76fad0c-d9ee-4314-a9d6-de881cb417cb'	System	28 Dec 2020 22:59:26
User entered 'No (N)'	System	28 Dec 2020 22:59:26

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-12-28T17:59:23', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a76fad0c-d9ee-4314-a9d6-de881cb417cb' User entered '28 Dec 2020 17:59:23'	System	28 Dec 2020 22:59:26
	System	28 Dec 2020 22:59:26

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-03T12:00:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9de9f38b-fbf3-4393-9dd7-ed4ccf82c3dd' User entered 'No (N)'	System	03 Jan 2021 17:00:57
	System	03 Jan 2021 17:00:57

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-03T12:00:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9de9f38b-fbf3-4393-9dd7-ed4ccf82c3dd'	System	03 Jan 2021 17:00:57
User entered 'No (N)'	System	03 Jan 2021 17:00:57

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-03T12:00:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9de9f38b-fbf3-4393-9dd7-ed4ccf82c3dd'	System	03 Jan 2021 17:00:57
User entered '03 Jan 2021 12:00:51'	System	03 Jan 2021 17:00:57

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-08T08:18:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2bfa4463-6028-4637-a33a-f26c3e32e948'	System	08 Jan 2021 13:18:58
User entered 'No (N)'	System	08 Jan 2021 13:18:58

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-08T08:18:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2bfa4463-6028-4637-a33a-f26c3e32e948'	System	08 Jan 2021 13:18:58
User entered 'No (N)'	System	08 Jan 2021 13:18:58

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-08T08:18:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2bfa4463-6028-4637-a33a-f26c3e32e948' User entered '08 Jan 2021 08:18:55'	System	08 Jan 2021 13:18:58
	System	08 Jan 2021 13:18:58

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-15T07:34:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4f3c3e78-d69f-4dc7-b752-be1089d27fdc' User entered 'No (N)'	System	15 Jan 2021 12:34:49
	System	15 Jan 2021 12:34:49

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-15T07:34:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4f3c3e78-d69f-4dc7-b752-be1089d27fdc' User entered 'No (N)'	System	15 Jan 2021 12:34:49
	System	15 Jan 2021 12:34:49

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-15T07:34:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4f3c3e78-d69f-4dc7-b752-be1089d27fdc' User entered '15 Jan 2021 07:34:46'	System	15 Jan 2021 12:34:49

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-26T10:46:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4618f21a-f5a8-4d73-b600-73ba932bb9e2'	System	26 Jan 2021 15:46:28
User entered 'No (N)'	System	26 Jan 2021 15:46:28

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-26T10:46:23', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4618f21a-f5a8-4d73-b600-73ba932bb9e2'	System	26 Jan 2021 15:46:28
User entered 'No (N)'	System	26 Jan 2021 15:46:28

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-01-26T10:46:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4618f21a-f5a8-4d73-b600-73ba932bb9e2' User entered '26 Jan 2021 10:46:25'	System	26 Jan 2021 15:46:28
	System	26 Jan 2021 15:46:28

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-01T18:26:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '720ab8c4-7007-4c34-9578-4293af789b9f' User entered 'No (N)'	System	01 Feb 2021 23:26:38
	System	01 Feb 2021 23:26:38

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-01T18:26:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '720ab8c4-7007-4c34-9578-4293af789b9f' User entered 'No (N)'	System	01 Feb 2021 23:26:38
	System	01 Feb 2021 23:26:38

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-01T18:26:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '720ab8c4-7007-4c34-9578-4293af789b9f' User entered '01 Feb 2021 18:26:36'	System	01 Feb 2021 23:26:38
	System	01 Feb 2021 23:26:38

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-08T18:01:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e7dc1eb9-5b74-4c64-ba1f-f5384a6f3013'	System	08 Feb 2021 23:05:36
User entered 'No (N)'	System	08 Feb 2021 23:05:36

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-08T18:01:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e7dc1eb9-5b74-4c64-ba1f-f5384a6f3013'	System	08 Feb 2021 23:05:36
User entered 'No (N)'	System	08 Feb 2021 23:05:36

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-08T18:01:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e7dc1eb9-5b74-4c64-ba1f-f5384a6f3013'	System	08 Feb 2021 23:05:36
User entered '08 Feb 2021 18:01:56'	System	08 Feb 2021 23:05:36

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-14T12:03:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1928ff85-17da-48c6-b28e-8994c1b65a0f'	System	14 Feb 2021 17:09:01
User entered 'No (N)'	System	14 Feb 2021 17:09:01

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-14T12:03:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1928ff85-17da-48c6-b28e-8994c1b65a0f'	System	14 Feb 2021 17:09:01
User entered 'No (N)'	System	14 Feb 2021 17:09:01

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-14T12:03:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1928ff85-17da-48c6-b28e-8994c1b65a0f' User entered '14 Feb 2021 12:03:29'	System	14 Feb 2021 17:09:01
	System	14 Feb 2021 17:09:01

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-23T10:08:18-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d40f8d7-0b5a-4f86-b61d-30268bda711a'	System	23 Feb 2021 15:08:36
User entered 'No (N)'	System	23 Feb 2021 15:08:36

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-23T10:08:21-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d40f8d7-0b5a-4f86-b61d-30268bda711a' User entered 'No (N)'	System	23 Feb 2021 15:08:36
	System	23 Feb 2021 15:08:36

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-02-23T10:08:27-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d40f8d7-0b5a-4f86-b61d-30268bda711a'	System	23 Feb 2021 15:08:36
User entered '23 Feb 2021 15:08:27'	System	23 Feb 2021 15:08:36

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:24-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '000efec8-2bb9-4bbf-bf2a-ab021dd5a8e7'	System	02 Mar 2021 16:59:34
User entered 'No (N)'	System	02 Mar 2021 16:59:34

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:26-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '000efec8-2bb9-4bbf-bf2a-ab021dd5a8e7'	System	02 Mar 2021 16:59:34
User entered 'No (N)'	System	02 Mar 2021 16:59:34

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:29-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '000efec8-2bb9-4bbf-bf2a-ab021dd5a8e7'	System	02 Mar 2021 16:59:34
User entered '02 Mar 2021 11:59:29'	System	02 Mar 2021 16:59:34

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-09T11:59:19-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a1b49b4d-6708-41e9-a856-d5fd17e42194'	System	09 Mar 2021 16:59:32
User entered 'No (N)'	System	09 Mar 2021 16:59:32

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-09T11:59:21-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a1b49b4d-6708-41e9-a856-d5fd17e42194'	System	09 Mar 2021 16:59:32
User entered 'No (N)'	System	09 Mar 2021 16:59:32

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-09T11:59:24-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a1b49b4d-6708-41e9-a856-d5fd17e42194' User entered '09 Mar 2021 11:59:24'	System	09 Mar 2021 16:59:32
	System	09 Mar 2021 16:59:32

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-16T12:05:26-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '80679a4e-bdb7-4b8f-8c68-b6135c7d64f0'	System	16 Mar 2021 16:09:00
User entered 'No (N)'	System	16 Mar 2021 16:09:00

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-16T12:05:28-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '80679a4e-bdb7-4b8f-8c68-b6135c7d64f0'	System	16 Mar 2021 16:09:00
User entered 'No (N)'	System	16 Mar 2021 16:09:00

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-16T12:05:31-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '80679a4e-bdb7-4b8f-8c68-b6135c7d64f0' User entered '16 Mar 2021 12:05:31'	System	16 Mar 2021 16:09:00
	System	16 Mar 2021 16:09:00

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-23T12:24:58-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d302728-cb77-4373-a83c-8e1aeb8bcf05'	System	23 Mar 2021 16:25:06
User entered 'No (N)'	System	23 Mar 2021 16:25:06

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-23T12:25:00-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d302728-cb77-4373-a83c-8e1aeb8bcf05'	System	23 Mar 2021 16:25:06
User entered 'No (N)'	System	23 Mar 2021 16:25:06

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-23T12:25:03-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d302728-cb77-4373-a83c-8e1aeb8bcf05'	System	23 Mar 2021 16:25:06
User entered '23 Mar 2021 12:25:03'	System	23 Mar 2021 16:25:06

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-26T07:05:11-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e9d7af76-9171-44bb-b7a5-7110173ae1e2'	System	26 Mar 2021 11:05:29
User entered 'No (N)'	System	26 Mar 2021 11:05:29

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-26T07:05:21-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e9d7af76-9171-44bb-b7a5-7110173ae1e2'	System	26 Mar 2021 11:05:29
User entered 'No (N)'	System	26 Mar 2021 11:05:29

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-26T07:05:27-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e9d7af76-9171-44bb-b7a5-7110173ae1e2' User entered '26 Mar 2021 07:05:27'	System	26 Mar 2021 11:05:29
	System	26 Mar 2021 11:05:29

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-05T18:07:56-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c13451ba-fe0b-4021-8cf6-9a2b1b0101aa'	System	05 Apr 2021 22:10:24
User entered 'No (N)'	System	05 Apr 2021 22:10:24

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-05T18:07:58-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c13451ba-fe0b-4021-8cf6-9a2b1b0101aa'	System	05 Apr 2021 22:10:24
User entered 'No (N)'	System	05 Apr 2021 22:10:24

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-05T18:08:00-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c13451ba-fe0b-4021-8cf6-9a2b1b0101aa'	System	05 Apr 2021 22:10:24
User entered '05 Apr 2021 18:08:00'	System	05 Apr 2021 22:10:24

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-11T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '97a3cf97-e3dc-4786-a4b1-5f86ca59de75'	System	11 Apr 2021 16:08:00
User entered 'No (N)'	System	11 Apr 2021 16:08:00

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-11T12:05:20-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '97a3cf97-e3dc-4786-a4b1-5f86ca59de75'	System	11 Apr 2021 16:08:00
User entered 'No (N)'	System	11 Apr 2021 16:08:00

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-11T12:05:24-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '97a3cf97-e3dc-4786-a4b1-5f86ca59de75'	System	11 Apr 2021 16:08:00
User entered '11 Apr 2021 12:05:24'	System	11 Apr 2021 16:08:00

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-19T17:59:31-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fda5d90d-1baa-4189-8d75-bc8b0b2a085b'	System	19 Apr 2021 21:59:42
User entered 'No (N)'	System	19 Apr 2021 21:59:42

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-19T17:59:33-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fda5d90d-1baa-4189-8d75-bc8b0b2a085b'	System	19 Apr 2021 21:59:42
User entered 'No (N)'	System	19 Apr 2021 21:59:42

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-19T17:59:38-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fda5d90d-1baa-4189-8d75-bc8b0b2a085b'	System	19 Apr 2021 21:59:42
User entered '19 Apr 2021 17:59:38'	System	19 Apr 2021 21:59:42

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-25T12:03:20-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd84cbb5c-4553-40ba-a90c-04cfa4f5c3a1'	System	25 Apr 2021 16:07:52
User entered 'No (N)'	System	25 Apr 2021 16:07:52

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-25T12:03:22-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd84cbb5c-4553-40ba-a90c-04cfa4f5c3a1'	System	25 Apr 2021 16:07:52
User entered 'No (N)'	System	25 Apr 2021 16:07:52

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-04-25T12:03:25-04:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd84cbb5c-4553-40ba-a90c-04cfa4f5c3a1'	System	25 Apr 2021 16:07:52
User entered '25 Apr 2021 12:03:25'	System	25 Apr 2021 16:07:52

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:38:14

**US3522529**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:02:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:01

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 20:29:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:34-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e4d90c07-4bc7-457c-8184-04854a9f428f' User entered 'Yes (Y)'	System	02 Mar 2021 17:00:04
	System	02 Mar 2021 17:00:04

US3522529

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:01

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:29:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:38-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e4d90c07-4bc7-457c-8184-04854a9f428f' User entered 'Yes (Y)'	System	02 Mar 2021 17:00:04
	System	02 Mar 2021 17:00:04

US3522529

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:29:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2021-03-02T11:59:53-05:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e4d90c07-4bc7-457c-8184-04854a9f428f' User entered '02 Mar 2021 11:59:53'	System	02 Mar 2021 17:00:04
	System	02 Mar 2021 17:00:04

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:40:03

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '2 Dec 2020'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:40:03

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:40:03

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:40:03

US3522529

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:34:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	02 Dec 2020 16:40:07

US3522529

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:20:50
User entered '1'	System	02 Dec 2020 16:40:07

US3522529

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	05 Jan 2021 15:52:18

US3522529

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '7 Jan 2021' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Jan 2021 22:29:26
User entered '6 Jan 2021' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 20:39:15
User entered '5 Jan 2021'	Yaman Ahmed (b) (4) (b) (4)	05 Jan 2021 15:52:18

US3522529

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Jan 2021 22:29:26
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	05 Jan 2021 15:52:18

US3522529

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Jan 2021 22:29:26
User entered '1st attempt on 05 Jan 2021; 2nd attempt 06 Jan 2021; voicemail box full, couldn't leave a voicemail, so texted her to primary phone number. Email from yesterday (05 Jan 2021) was not responded to' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 20:39:15
User entered 'voicemail box full, couldn't leave a voicemail, emailed her instead'	Yaman Ahmed (b) (4) (b) (4)	05 Jan 2021 15:52:18

US3522529

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	07 Jan 2021 22:29:31

US3522529

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
User entered '1'	System	07 Jan 2021 22:29:31

US3522529

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:19
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 14:12:33

US3522529

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:19
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '4 Feb 2021'	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 14:12:33

US3522529

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:19
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 14:12:33

US3522529

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:19
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'left vm'	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 14:12:33

US3522529

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:35:24
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 20:39:21

US3522529

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
User entered 'I'	System	04 Mar 2021 20:39:21

US3522529

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:36:36
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 20:42:18

US3522529

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:36:36
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User entered '9 Mar 2021' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:02:31
User entered '4 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 20:42:18

US3522529

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:36:36
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Yaman Ahmed (b) (4)	04 Mar 2021 20:42:18

US3522529

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:36:36
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 22:21:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '2ND ATTEMPT LEFT A VOICEMAIL' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:02:31
User entered 'left a voicemail'	Yaman Ahmed (b) (4)	04 Mar 2021 20:42:18
	(b) (4)	

US3522529

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:36:40
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:33
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 22:28:48

US3522529

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:45:50
User entered 'I'	System	09 Mar 2021 22:28:48

US3522529

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:36:53
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:26

US3522529

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:36:53
User entered '26 Mar 2021'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:26

US3522529

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[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 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:36:53
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:26

US3522529

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered 'VISIT4'	System	26 Mar 2021 12:15:26

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered empty.	System	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered empty.	System	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered empty.	System	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered empty.	System	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:10:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered empty.	System	31 Mar 2021 15:19:25

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43

US3522529

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43

US3522529

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:12:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:39
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:37:02
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:34

US3522529

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:12:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:39
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:19:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:37:02
User entered '26 Mar 2021'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:34

US3522529

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:37:06
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:47

US3522529

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:37:06
User entered '26 Mar 2021'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:47

US3522529

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:37:06
User entered '08:12'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:47

**US3522529**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered '26 Mar 2021 08:12'	System	26 Mar 2021 12:15:47

US3522529

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:37:11
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:15:52

US3522529

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:55:43
User entered '1'	System	26 Mar 2021 12:15:52

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:01

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:38:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:01

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:38:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '15:30' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:10
User entered '15:45'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:42
User entered '16 Nov 2020 15:30'	System	19 Nov 2020 16:11:10
User entered '16 Nov 2020 15:45'	System	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:01

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:38:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:38:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'Day 1 (Day 1)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:53
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered '1'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered '%'	System	19 Nov 2020 16:08:00
User entered empty.	System	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:02:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:27
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:08:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:57

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered '97'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered '%'	System	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered '98.8' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:02:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:31
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:49
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:15:01

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered '17 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered '98'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered '%'	System	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:02:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:36
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:54
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:21

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'Day 4 (Day 4)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered '18 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered '98'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered '%'	System	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered '98' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:02:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:45
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:40:58
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:17:46

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered '19 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered '99'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered '%'	System	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:02:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:20:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:06:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:49:06
DataPoint activated with code reason code Data required.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 15:10:50
DataPoint inactivated with code reason code Data not required.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:41:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:36

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:56:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:02:01

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:21:01
User entered '0'	System	24 Nov 2020 18:33:44

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '18 Nov 2020'	(b) (4) Sharon Mathys (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '20 Nov 2020'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:02:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:02:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Clinic (Clinic)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered 'SICKD1'	System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '15:40'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered '16 Nov 2020 15:40'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '65' in	(b) (4) Sharon Mathys (b) (4)	19 Nov 2020 16:11:04
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '175' lb	(b) (4) Sharon Mathys (b) (4)	19 Nov 2020 16:11:04
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '98.8' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '97'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered 'bpm'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered 'breaths/min'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '116'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered 'mmHg'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '80'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
User entered 'mmHg'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:08

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:08

US3522529

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:02:01

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:22

US3522529

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:57:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:22

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:02
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:02
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4)	24 Nov 2020 19:01:34

**US3522529**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:02:01**

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Nov 2020 19:01:34

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

---

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Respiratory Rate units](#)

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Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:01

[Diastolic Blood Pressure units](#)

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Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

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US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:08
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:43

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:08
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:43

US3522529

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:02:01

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 19:01:55

US3522529

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:02:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:58:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) Sharon Mathys (b) (4)	24 Nov 2020 19:01:55

US3522529

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:00:57
User entered 'Yes (Y)'	Alandra White (b) (4)	26 Mar 2021 12:16:12

US3522529

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:00:57
User entered '26 Mar 2021'	Alandra White (b) (4)	26 Mar 2021 12:16:12

US3522529

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[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 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:00:57
User entered 'Clinic (Clinic)'	Alandra White (b) (4)	26 Mar 2021 12:16:12

US3522529

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User entered 'UNBLND_DECIDE'	System	26 Mar 2021 12:16:12

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
Signature has been broken.	Alandra White (b) (4)	26 Mar 2021 12:16:30
User entered '26 Mar 2021' reason for change: Data Entry Error	Alandra White (b) (4)	26 Mar 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered empty.	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[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 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered '0'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'Amendment 5 (Amendment 5)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 10:46:46
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'previous amendment 5 unblinding ' (Site from System).	Alandra White (b) (4) (b) (4)	26 Mar 2021 12:17:07
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	26 Mar 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:25:27
User entered '29 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'mRNA-1273 (mRNA-1273)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'mRNA-1273 (mRNA-1273)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'mRNA-1273 (mRNA-1273)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:38
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:25:27
User entered 'No (N)'	Sharon Mathys (b) (4)	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User entered empty.	System	17 Mar 2021 16:50:49

US3522529

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User entered empty.	System	17 Mar 2021 16:50:49

US3522529

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:22
User entered 'Yes (Y)'	Alandra White (b) (4)	26 Mar 2021 12:17:21

US3522529

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:22
User entered '26 Mar 2021'	Alandra White (b) (4)	26 Mar 2021 12:17:21

US3522529

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:22
User entered '08:12'	Alandra White (b) (4)	26 Mar 2021 12:17:21

US3522529

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User entered '26 Mar 2021 08:12'	System	26 Mar 2021 12:17:21

US3522529

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:27
User entered 'Yes (Y)'	Alandra White (b) (4)	26 Mar 2021 12:17:34

US3522529

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:27
User entered '26 Mar 2021'	Alandra White (b) (4)	26 Mar 2021 12:17:34

US3522529

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:49:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:04:27
User entered '08:08'	Alandra White (b) (4)	26 Mar 2021 12:17:34

US3522529

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:43:06
User entered '26 Mar 2021 08:08'	System	26 Mar 2021 12:17:34

US3522529

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:02:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:51
User closed query '? Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 02:56:22
Query '? Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'added headache and fatigue for dose 1 and 2. participant has a hx of migraines' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:10:12
User opened query '? Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 14:17:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:32
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:05:56

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:56:48
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:56:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:37
User entered 'USA-US131-2020-mRNA-1273-P301000006'	System	24 Sep 2020 01:47:33
User entered 'New'	(b) (4), (b) (6)	24 Sep 2020 01:47:33

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 14:12:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 14:12:20
Data point term sent to Coder	System	28 Dec 2020 14:10:59
Coding entries removed.	(b) (4), (b) (6)	28 Dec 2020 14:10:24
User entered 'herniated disc' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Dec 2020 14:10:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 21:03:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 21:03:25
Data point term sent to Coder	System	22 Oct 2020 17:18:09
DataPoint Un-verified.	Sharon Mathys (b) (4)	22 Oct 2020 17:17:55
Coding entries removed.	(b) (4)	22 Oct 2020 17:17:55
User entered 'Degenerative Disc Disease (Multilevel)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:17:55
DataPoint Verified.	(b) (4)	08 Oct 2020 20:05:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:31:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:31:52
Data point term sent to Coder	System	24 Sep 2020 15:30:37

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2001 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
	(b) (4)	
User entered 'HERNIATED Disc' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLG: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 22:08:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 22:08:47
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 22:07:58
User entered 'Hernia'	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:30:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 15:30:11
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:30:11
User entered '23 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:30:11
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:29:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:29:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:02:01**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:07:42

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US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
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).	System	24 Sep 2020 15:29:52
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 by data change (Site from System).	System	24 Sep 2020 15:29:52
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	23 Sep 2020 22:07:42
User entered '1'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '23 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Sep 2020 22:08:40
User entered '1' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:08:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Sep 2020 22:07:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HERNIATED DISC. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 03:30:50
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HERNIATED DISC. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' answered with 'updated to reflect concomittant medication rationale' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 14:10:42
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HERNIATED DISC. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 01:49:35
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: SAE Narrative = WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 07:05:56
Query 'Per DM CLR: SAE Narrative = WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF.' answered with 'blood work / phlebotomy updated in con- procedure' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 14:14:15
User opened query 'Per DM CLR: SAE Narrative = WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 01:49:30
User closed query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:43:31

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' answered with 'previous query response: They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present.' From narrative "ENDOCRINOLOGIST DETERMINED THAT THE ELECTOLYTE IMBALANCE WAS IN ACTUALITY A LAB ERROR '" (Site from DM).	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:49:02
User opened query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 01:41:49
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:48:55
User closed query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:51:56
User closed query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:51:52
User closed query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:40:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2034 of 2758

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' answered with 'They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present. Reason for going to Hospital was (told to us at time) Herniated disc. During stay MRI diagnosed Degenerative Disc Disease (Multilevel)' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:24:43
Query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' answered with 'They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:23:54

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 AFTER PACKING AND MOVING RECENTLY AND DEVELEOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. COVID 19 NP SWAB WAS GIVEN ON INTAKE AND RESULTS WERE NEGATIVE. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL. During admittance, endocrinologist determined that the electolyte imbalance was in actuality a lab error due to rapid normalizaton of albumin levels in 12 hours.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:21:35

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
<p>Query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' answered with 'MRI OF THE LUMBAR SPINE WITHOUT CONTRAST &lt;br /&gt; &lt;br /&gt;History: Back pain and radiculopathy &lt;br /&gt; &lt;br /&gt;Comparison: None &lt;br /&gt; &lt;br /&gt;Technique: T1, T2 , STIR sagittal and T1 and T2 axial images of the lumbar &lt;br /&gt; spine have been performed. &lt;br /&gt; &lt;br /&gt;Comments: The lumbar vertebral body heights are maintained. The distal spinal &lt;br /&gt; cord is normal in signal and location. There is no bone marrow or ligament &lt;br /&gt; edema. There is degeneration of the disks and disc space narrowing at L3-L4 &lt;br /&gt; through L5-S1. The distal spinal cord terminates at L1. The spinal alignment &lt;br /&gt; is intact. Advanced degenerative change is worst at L4/L5. Schmorl's nodes are &lt;br /&gt; noted at L2 and T12. &lt;br /&gt; &lt;br /&gt;Axial images: &lt;br /&gt; &lt;br /&gt;T12-L1: No central canal stenosis. &lt;br /&gt;L1-L2: No central canal stenosis. &lt;br /&gt;L2-3: Mild disc bulge and facet degenerative change. No central canal &lt;br /&gt; stenosis. &lt;br /&gt;L3-L4: Mild disc bulge and facet degenerative change. No significant central &lt;br /&gt; canal stenosis. &lt;br /&gt;L4-L5: Diffuse disc bulge and facet hypertrophy. No central canal stenosis. &lt;br /&gt;Lateral bulges result in mild foraminal narrowing. &lt;br /&gt;L5-S1: Facet degenerative change is mild to moderate. There is no high-grade &lt;br /&gt; central canal stenosis. Lateral protrusions result in mild bilateral foraminal &lt;br /&gt; narrowing. &lt;br /&gt; &lt;br /&gt;The paraspinous soft tissues appear unremarkable. &lt;br /&gt; &lt;br /&gt;IMPRESSION: Multilevel degenerative change involving the disks and endplates. &lt;br /&gt;There is no large disc herniation or high-grade central canal stenosis. &lt;br /&gt;' (Site from Safety). DataPoint Un-verified.</p>	<p>Sharon Mathys (b) (4) (b) (4)</p>	<p>22 Oct 2020 17:19:05</p>
	<p>Sharon Mathys (b) (4) (b) (4)</p>	<p>22 Oct 2020 17:17:55</p>

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 after PACKING AND MOVING RECENTLY AND DEVELEOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. COVID 19 NP SWAB WAS GIVEN ON INTAKE AND RESULTS WERE NEGATIVE. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:06:32
User opened query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:06:20
User opened query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:06:05
User opened query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:05:57
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:23
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:19
Query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:15
Query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:13
Query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '9/21 np swab done on intake with negative results' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	06 Oct 2020 14:54:04

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 FOR A HERNIATED DISC, AFTER PACKING AND MOVING RECENTLY AND DEVELOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. Covid 19 NP swab was given on intake and results were negative. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	06 Oct 2020 14:53:40
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:18:16
User opened query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:18:01
User opened query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:16:45
User opened query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:16:34

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:16:27
User entered 'WENT TO HOSPITAL FOR A HERNIATED disc, after packing and moving recently and developing severe low back pain. Was admitted due to electrolyte abnormalities in lab with Calcium 5.1, K + 3.1, Mg 1.1. No nausea/vomiting/diarrhea. was given IV correction of Magnesium/potassium/calcium. sent home in late afternoon on sep 23, 2020 with prednisone dose, ultram and Robaxin for pain. (see concom. meds). Feeling better, and wants to still participate in trial.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Sep 2020 22:08:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Sep 2020 22:08:40
User entered 'Went to hospital for a hernia, was admitted due to low electrolytes. Still in hospital at day of contact Sept 23rd.' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:08:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Sep 2020 22:07:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:02:01**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:07:42

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**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:02:01**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:07:42

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**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:02:01**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 22:07:42

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US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 00:33:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 00:33:40
Data point term sent to Coder	System	21 Apr 2021 19:57:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered 'HEADACHE moderate' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 14:42:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 14:42:26
Data point term sent to Coder	System	14 Oct 2020 14:40:44
User entered 'Headache day 8 and day 9'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:09
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
User entered empty.	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4) System	14 Oct 2020 14:40:27
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:27
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	14 Oct 2020 14:39:45
User entered '11 Sep 2029'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Apr 2021 19:57:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 19:57:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 19:57:21
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Apr 2021 19:57:21
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered ':00' (non-conformant).	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
User entered empty.	System	21 Apr 2021 19:57:40
User entered '10 Sep 2020 :00' (non-conformant).	System	21 Apr 2021 19:57:21
User entered empty.	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:46:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:45:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Nov 2020 19:47:10
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'Updated to related to investigational product' (Site from DM).	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:41:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Oct 2020 14:40:07
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:07
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Oct 2020 14:39:45
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 19:57:21
User entered 'Patient has a history of migraines' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'PATIENT EXPERIENCED mild HEADACHE DAY 8 AND DAY 9.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:07
User entered 'Patient experienced headache day 8 and day 9.'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
User entered '0'	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53
User entered '0'	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:21:53

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 04:46:08
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'No. Deemed related to IP as it was a continuation from the injection' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	01 Dec 2020 12:58:42
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:14:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:30:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:30:37
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:15:19

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match.  ' answered with 'Updated to match eDiary Day 8 which pt forgot to complete.' (Site from DM). Data point term sent to Coder Coding entries removed.	Alandra White (b) (4) (b) (4) System Alandra White (b) (4) (b) (4)	05 Nov 2020 19:58:41 05 Nov 2020 19:58:06 05 Nov 2020 19:58:00 05 Nov 2020 19:58:00
User entered 'MUSCLE ACHES ALL OVER BODY DAY 8' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	05 Nov 2020 19:58:00
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:03:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:51:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:51:39
Data point term sent to Coder	System	14 Oct 2020 14:47:58
User entered 'Muscle aches day 8'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
User entered empty.	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:39:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '28 Oct 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:39:44
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
User entered empty.	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:48:36
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'changed to not related and investigational product as related' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:47:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:47:21
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:41:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:02:01**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'l'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 16:39:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'patient states she is still experiencing mild muscle aches on day 8 after injection.'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
User entered '0'	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01
User entered '0'	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:01

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:38:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:38:07
Data point term sent to Coder	System	24 Nov 2020 18:37:38
User entered 'Fatigue'	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
User entered empty.	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
User entered empty.	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:37:37
User entered empty.	System	24 Nov 2020 18:37:37
	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:37:37
User entered empty.	System	24 Nov 2020 18:37:37
	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:37:37
User entered empty.	System	24 Nov 2020 18:37:37
	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 18:37:37
User entered empty.	System	24 Nov 2020 18:37:37
	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
User entered '0'	System	24 Nov 2020 18:39:10

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08
User entered '0'	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:08

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:39:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:39:03
Data point term sent to Coder	System	24 Nov 2020 18:38:41
User entered 'Nasal Congestion'	Sharon Mathys (b) (4)	24 Nov 2020 18:38:19
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
User entered empty.	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
User entered empty.	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
User entered '0'	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17
User entered '0'	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:17

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:41:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:41:41
Data point term sent to Coder	System	24 Nov 2020 18:39:43
User entered 'Sore Throat'	Sharon Mathys (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
User entered empty.	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '17 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
User entered empty.	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:59:58
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
User entered '0'	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25
User entered '0'	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:25

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Electrolyte imbalance NEC, PT: Electrolyte imbalance, LLT: Electrolyte imbalance - version MedDRA\23.0.	(b) (4)	
	Coder Import (b) (4)	22 Dec 2020 15:32:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Dec 2020 15:32:46
	(b) (4)	
Data point term sent to Coder	System	22 Dec 2020 15:32:18
User entered 'electrolyte imbalance'	(b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
User entered empty.	System	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
User entered empty.	System	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	05 Mar 2021 15:10:21
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:58:36
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:28:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
User entered '0'	System	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32
User entered '1'	System	22 Dec 2020 15:31:27

US3522529

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:32

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:32:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:32:02
Data point term sent to Coder	System	21 Apr 2021 20:01:30
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 20:01:17
User entered 'FATIGUE - mild' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:01:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:43:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:43:57
Data point term sent to Coder	System	21 Apr 2021 12:42:53
User entered 'Fatigue'	Sharon Mathys (b) (4)	21 Apr 2021 12:42:36
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:17
User entered '07 Sep 2020'	Sharon Mathys (b) (4)	21 Apr 2021 12:42:36
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
User entered empty.	System	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '10 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
User entered empty.	System	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Related (RELATED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'None (NONE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:49
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '1'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
User entered '0'	System	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39
User entered '0'	System	21 Apr 2021 12:42:36

US3522529

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:39

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:32:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:32:02
Data point term sent to Coder	System	21 Apr 2021 20:06:54
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 20:06:20
User entered 'FATIGUE - mild' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:06:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 14:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 14:29:45
Data point term sent to Coder	System	21 Apr 2021 14:21:12
User entered 'Fatigue'	Sharon Mathys (b) (4)	21 Apr 2021 14:20:56
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:47:51
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 13:41:24
User closed query 'Per CDM: Please note that per Diary dose 2, Fatigue was started on 12Oct 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please note that per Diary dose 2, Fatigue was started on 12Oct 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.' answered with 'corrected. first date with that grade was D7. Was told to combine grades' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 03:59:02
DataPoint Un-verified.	Sharon Mathys (b) (4)	27 Apr 2021 12:48:10
Signature has been broken.	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Apr 2021 12:48:06
User opened query 'Per CDM: Please note that per Diary dose 2, Fatigue was started on 12Oct 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.' (Site from DM).	(b) (4)	
DataPoint Verified.	Sharon Mathys (b) (4)	27 Apr 2021 12:48:06
User signature succeeded.	(b) (4)	
User entered '14 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Apr 2021 12:48:06
User entered '12 Oct 2020'	(b) (4), (b) (6)	23 Apr 2021 02:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered '12 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 20:06:20
	Sharon Mathys (b) (4)	21 Apr 2021 14:20:56
	(b) (4)	

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:02:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
User entered empty.	System	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '16 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
User entered empty.	System	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:02:01**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Related (RELATED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '1'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:18:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
User entered '0'	System	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51
User entered '0'	System	21 Apr 2021 14:20:56

US3522529

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:51

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:06:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:06:04
Data point term sent to Coder	System	21 Apr 2021 19:59:26
User entered 'Headache mild'	(b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
User entered empty.	System	21 Apr 2021 19:58:30

**US3522529**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 08:02:01**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
User entered empty.	System	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:09:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:09:13
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Participant has a history of migraines'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 19:58:42
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
User entered '0'	System	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05
User entered '0'	System	21 Apr 2021 19:58:30

US3522529

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:05

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 06:35:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 06:35:56
Data point term sent to Coder	System	21 Apr 2021 20:08:55
User entered 'Headache - Moderate'	(b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
User entered empty.	System	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
User entered empty.	System	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	21 Apr 2021 20:08:51
User entered '1' reason for change: Data Entry Error	System	21 Apr 2021 20:08:51
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 20:08:45
User entered '0'	System	21 Apr 2021 20:08:45
	(b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:05:54
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:18:54
User entered 'Pt has medical history of migraines'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
User entered '0'	System	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58
User entered '0'	System	21 Apr 2021 20:08:45

US3522529

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:02:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:22:58

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:02:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:17:52
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:00:42

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Dec 2020 22:49:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:49:47
Data point term sent to Coder	System	22 Dec 2020 15:29:04
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 15:28:24
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:18:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:40:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:40:32
Data point term sent to Coder	System	23 Oct 2020 14:15:06
Data point term sent to Coder	System	23 Oct 2020 14:14:03
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:57:43

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'ibuprofen'	Coder Import (b) (4) (b) (4) System Alandra White (b) (4) (b) (4)	15 Sep 2020 13:57:43  15 Sep 2020 13:02:50 15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, generalized pain, back pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 08:58:58
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, generalized pain, back pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'fixed per query. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:28:51
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 15:28:24
User entered 'MIGRAINES/HEADACHES/generalized pain' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 15:28:24
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, generalized pain, back pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:38:59
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'MIGRAINES/HEADACHES/PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:14:07
User entered 'migraines/HEADACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES 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 HEADACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:08:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES 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 HEADACHES did not meet the AE reporting criteria.' answered with 'new AE completed for unsolicited headache day 8 and day 9' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:41:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES 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 HEADACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:03:22
User entered 'pain/headaches'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

PRODUCTION RELEASE (v12.003  
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2411 of 2758

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered '800'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'as needed (PRN)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User entered '4 Sep 2020'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User entered '0'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:27:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, if this is related to AE#2 HEADACHE DAY 8 and DAY 9, note that this CM was given at Day 8 and it is reported as not a solicited event in AE eCRF. Review if this is considered as unsolicited event per protocol. If yes, please update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 07:22:54
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, if this is related to AE#2 HEADACHE DAY 8 and DAY 9, note that this CM was given at Day 8 and it is reported as not a solicited event in AE eCRF. Review if this is considered as unsolicited event per protocol. If yes, please update this field to No. Else, provide clarification.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 15:28:24
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 15:28:24
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, if this is related to AE#2 HEADACHE DAY 8 and DAY 9, note that this CM was given at Day 8 and it is reported as not a solicited event in AE eCRF. Review if this is considered as unsolicited event per protocol. If yes, please update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:48:05
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:18:02
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

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**US3522529**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:02:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ZOLMITRIPTAN, PRODUCTSYNONYM: ZOMIG-ZMT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:11:37
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 Oct 2020 14:11:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 14:10:57 23 Oct 2020 14:10:16
User entered 'ZOMIG-ZMT' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:10:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ZOLMITRIPTAN, PRODUCTSYNONYM: ZOMIG - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:26:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:26:52
Data point term sent to Coder	System	16 Sep 2020 18:26:26
User entered 'Zomig'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'Migraines'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered '5'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered '1'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:05
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:18:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:23
Data point term sent to Coder	System	22 Oct 2020 17:09:58
User entered 'MAGNESIUM sulfate' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:09:24
Data point term sent to Coder	System	22 Oct 2020 17:06:52
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:06:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:28:47
Data point term sent to Coder	System	24 Sep 2020 15:31:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
User entered 'Magnesium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:59:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE added to patient chart. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:33:13
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:49:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 00:18:47
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 08:24:51
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:06:28
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	Yaman Ahmed (b) (4)	21 Oct 2020 17:19:34

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). User entered 'Electrolyte Imbalance'	(b) (4), (b) (6)	20 Oct 2020 15:31:22
	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered '2' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'unknown'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'g (g)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'Other (OTHER)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'unknown'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'once (ONCE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'as needed (PRN)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered '21 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered '23 Sep 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:47
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:10
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:24:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:24:39
Data point term sent to Coder	System	12 Nov 2020 17:49:29
Datapoint queued for coding (5129522).	System	12 Nov 2020 17:48:34
Data point term sent to Coder	System	22 Oct 2020 17:12:01
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User entered 'POTASSIUM chloride' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 06:20:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 06:20:21
Data point term sent to Coder	System	24 Sep 2020 15:39:08
User entered 'Potassium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:42:52
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:12:43
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	(b) (4) Yaman Ahmed (b) (4)	21 Oct 2020 17:19:41
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:31:46
User entered 'Electrolyte Imbalance'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered '20' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'meq' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'once daily (QD)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown (UNKNOWN)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered '22 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:50
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User entered '1'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User entered '1'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:12
User entered '804 (804)'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:54:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:54:36
Data point term sent to Coder	System	22 Oct 2020 17:08:56
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User entered 'CALCIUM gluconate' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:50
Data point term sent to Coder	System	24 Sep 2020 15:41:16
User entered 'Calcium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:43:05
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	(b) (4) Yaman Ahmed (b) (4)	21 Oct 2020 17:19:47
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:32:09
User entered 'Electrolyte Imbalance'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'unknown'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'g (g)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'once (ONCE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'as needed (PRN)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered '21 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:18:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:14
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:12:03
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'was taken for less than 14 days' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 16:53:29
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:01:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:48:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:48:56
Data point term sent to Coder	System	24 Sep 2020 15:44:20
User entered 'Prednisone'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'Herniated Disc'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered '50' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	21 Oct 2020 16:52:55
User entered '20'	(b) (4) Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'once daily (QD)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 16:52:55
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered empty; reason for change Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 16:52:55
User entered 'tapering dose'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:50:58
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered '27 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:22:01
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:50:58
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:25
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User entered '1'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User entered '1'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:16
User entered '804 (804)'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:21:45
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 Oct 2020 21:21:45
Data point term sent to Coder	System	29 Oct 2020 21:21:35
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:20:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:54:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:54:37
Data point term sent to Coder	System	07 Oct 2020 16:48:45
User closed query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	07 Oct 2020 16:48:42
Query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Tramadol' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 16:48:42
User entered 'Tramadol' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. (Site from System).	Coder Import (b) (4)	29 Sep 2020 08:22:47
Data point term sent to Coder	System	24 Sep 2020 15:45:24
User entered 'Ultram'	Sharon Mathys (b) (4)	24 Sep 2020 15:44:37
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User closed query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:56:56
Query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:20:57
User entered 'Herniated disc' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:20:39
User opened query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:33:13
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered '50'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'four times daily (QID)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User entered '4'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User entered '1'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:25
User entered '804 (804)'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
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)	29 Oct 2020 21:23:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:23:46
Data point term sent to Coder	System	29 Oct 2020 21:22:36
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:21:49
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)	24 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:45:53
Data point term sent to Coder	System	24 Sep 2020 15:45:25
User entered 'Robaxin'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User closed query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:57:07
Query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:22:01
User entered 'herniated disc' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:21:49
User opened query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:33:38
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:51:28
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:51:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:32
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:26
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 16:59:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:59:33
Data point term sent to Coder	System	14 Oct 2020 14:43:49
User entered 'Motrin'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHE, JOINT PAIN 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 or 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 HEADACHE, MUSCLE ACHE, JOINT PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 09:00:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHE, JOINT PAIN 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 or 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 HEADACHE, MUSCLE ACHE, JOINT PAIN did not meet the AE reporting criteria. ' answered with 'Headache and muscle ache was already in AE section based on e diary filed by pt. arthralgia added as AE based on diary also' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:38:22

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[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 time frame. If the HEADACHE, MUSCLE ACHE, JOINT PAIN 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 or 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 HEADACHE, MUSCLE ACHE, JOINT PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 17:21:15
User entered 'Headache, muscle ache, joint pain'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '600'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
User entered '1'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
User entered '1'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:29
User entered '804 (804)'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-DUR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:09:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:09:30
Data point term sent to Coder	System	22 Oct 2020 17:21:16
User entered 'Kdur'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'Presumed Electrolyte imbalance'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered '40'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'meq'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'once (ONCE)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 00:19:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:36
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 17:31:22
Data point term sent to Coder User entered 'flu vaccine'	(b) (4)	
	System	05 Nov 2020 17:30:46
	Alayna Wilder (b) (4)	05 Nov 2020 17:30:33
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'influenza'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'unk'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Other (OTHER)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'unk'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'once (ONCE)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '4 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '0'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'No (N)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered '4 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:07:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 07:24:08
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated to no as this is a preventative medication' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:39:24
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 15:38:58

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:50:35
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:25:37
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening MIGRAINES during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:55:44
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening MIGRAINES during this timeframe; update Con Med indication or provide clarification. ' answered with 'per EHR review, participant started treatment in 2018, date updated ' (Site from DM).	Alandra White (b) (4) (b) (4)	08 Apr 2021 13:40:18
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening MIGRAINES during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:11:53
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 21:00:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 21:00:41
Data point term sent to Coder	System	08 Mar 2021 20:59:54
User entered 'Botox'	(b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered '200'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	09 Mar 2021 22:21:59
User entered 'other (OTHER)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 22:21:59
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	08 Mar 2021 20:59:39
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'every three months'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:09:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
User entered '24 Jan 2019' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Alandra White (b) (4)	08 Apr 2021 13:43:48
Signature has been broken.	(b) (4)	
User entered '06 Aug 2018' reason for change: Data Entry Error	Alandra White (b) (4)	08 Apr 2021 13:39:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:45
User signature succeeded.	Marcus Zervos (b) (4)	31 Mar 2021 14:32:53
User entered '15 Oct 2020'	(b) (4), (b) (6)	12 Mar 2021 15:28:33
		08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:32:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:28:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 20:59:39

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 20:59:39

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 20:59:39

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANAFLEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:59:43
Data point term sent to Coder User entered 'Zanaflex'	System Alandra White (b) (4) (b) (4)	26 Mar 2021 11:59:08 26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'migraines'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered '4'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered empty.	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered empty.	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered empty.	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered '10 Mar 2021'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered '0'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered empty.	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:08:38
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	26 Mar 2021 11:58:54

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 11:58:54

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 11:58:54

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US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:01

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Mar 2021 11:58:54

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US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:02:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:26:38
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 16:53:05

**US3522529**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:02:01**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:13:32

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered 'lab work including phlebotomy.'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:13:32

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:09
User closed query 'Per DM CLR: Indication = Adverse Event. However please verify if this procedure/surgery was done for AE#1 (HERNIATED DISCE) or AE#7 (ELECTROLYTE IMBALANCE) . If Yes, note that the corresponding AEs "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. '(Site from DM). User signature succeeded.	(b) (4), (b) (6)	08 Mar 2021 10:09:26
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
Query 'Per DM CLR: Indication = Adverse Event. However please verify if this procedure/surgery was done for AE#1 (HERNIATED DISCE) or AE#7 (ELECTROLYTE IMBALANCE) . If Yes, note that the corresponding AEs "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	05 Mar 2021 15:10:59
User opened query 'Per DM CLR: Indication = Adverse Event. However please verify if this procedure/surgery was done for AE#1 (HERNIATED DISCE) or AE#7 (ELECTROLYTE IMBALANCE) . If Yes, note that the corresponding AEs "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. '(Site from DM).	(b) (4), (b) (6)	05 Mar 2021 14:58:58
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	05 Mar 2021 01:29:56
	(b) (4), (b) (6)	28 Dec 2020 14:13:32

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:33:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:13:32

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

**US3522529**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:02:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '23/Sep/2020 21:48'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:01

**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)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '25/Sep/2020 14:45'	System	25 Sep 2020 14:45:08

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:01

**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)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:09:16
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:45:08

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '07/Oct/2020 13:01'	System	07 Oct 2020 13:01:03

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:01

**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)	05 Mar 2021 17:26:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:39:53
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 13:01:03

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

**US3522529**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:02:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:42:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '23/Oct/2020 18:40'	(b) (4) System	23 Oct 2020 18:40:10

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:01

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:42:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:38:38
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 18:40:10

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6) '	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

**US3522529**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:02:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	29 Dec 2020 13:38:50
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:42:20
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '29/Dec/2020 13:38'	(b) (4) System	29 Dec 2020 13:38:50

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:01

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:42:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:26:38
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:38:50