

US3292128 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:22:59

All time stamps listed in this document are displayed in GMT

US3292128

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

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[Participant ID](#)

US3292128

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

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US3292128

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	DECREASED VISUAL ACUITY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	GENERALIZED GOUT
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	R ROTATOR CUFF SURGERY
Start date (dd MMM yyyy)	UN MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAY 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	L ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	RIGHT TORN ROTATOR CUFF
Start date (dd MMM yyyy)	UN MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAY 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	LEFT TORN ROTATOR CUFF
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	12 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:45
Height (xxx.x)	172.0 cm
Weight (xxx.x)	104.7 kg
BMI (xxx.x)	35.39075 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

11 AUG 2020

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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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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:47:50

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify** SHOPPING (GROCERY, RETAIL)  
2+ TIMES PER WEEK, WIFE IS  
PERSONAL CARETAKER FOR  
ANOTHER PATIENT

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:47:50

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<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<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>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

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

What was the participant's randomization number? 185731

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:00
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 AUG 2020

What was the treatment time? (00:00-23:59) 14:22 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 14:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

11 AUG 2020 13:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:48	11 AUG 2020 13:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:55

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**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

11 AUG 2020 15:02

PC Open Date & Time

11 AUG 2020 14:42

PC Close Date & Time

11 AUG 2020 17:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	11 AUG 2020 18:09
PC Open Date & Time	11 AUG 2020 18:07
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:31

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 12:23

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 14:35

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 15:03

PC Open Date & Time

11 AUG 2020 14:42

PC Close Date & Time

11 AUG 2020 17:12

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:09

PC Open Date & Time

11 AUG 2020 18:07

PC Close Date & Time

12 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 13:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:32

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 14:35

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**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 ☐

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 15:03
PC Open Date & Time	11 AUG 2020 14:42
PC Close Date & Time	11 AUG 2020 17:12

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**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 ☐

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:10
PC Open Date & Time	11 AUG 2020 18:07
PC Close Date & Time	12 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:58
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 4075

EAB) (1725)

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:33
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

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

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 14:36
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:10
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:36
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 18 AUG 2020 12:05

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 19 AUG 2020 12:13

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 AUG 2020 12:06

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 AUG 2020 12:13

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

21 AUG 2020 06:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 18 AUG 2020 12:06

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 19 AUG 2020 12:13

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

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US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 21 AUG 2020 06:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 22 AUG 2020 06:00

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 22 AUG 2020 23:59

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 23 AUG 2020 13:19

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 AUG 2020 12:12

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

---



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 25 AUG 2020 12:00

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 26 AUG 2020 19:07

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 27 AUG 2020 12:00

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 28 AUG 2020 12:27

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 29 AUG 2020 12:44

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 30 AUG 2020 13:00

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 31 AUG 2020 12:02

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 22

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 01 SEP 2020 14:28

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

---



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 23

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 02 SEP 2020 17:23

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 24

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 03 SEP 2020 12:00

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 25

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

04 SEP 2020 12:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 26

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 05 SEP 2020 12:05

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 27

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 06 SEP 2020 12:25

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 28

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 07 SEP 2020 12:00

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 29

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 08 SEP 2020 12:00

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 12:06
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 12:13
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 06:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 06:00
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 00:00
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 13:19
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 12:12
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 16
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 AUG 2020 19:07
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 17
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 12:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 18
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 12:27
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 19
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 12:45
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 20
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 13:00
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 21
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 22
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 14:29
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 23
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 17:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 24
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 12:00
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 25
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 12:00
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 26
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 12:05
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 27
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 12:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 28
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 12:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 29
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 12:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3292128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292128

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

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)	8 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:27
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:44
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

8 SEP 2020

---

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

---

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 12:14 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 12:14

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



US3292128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	8 SEP 2020 11:40

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	8 SEP 2020 11:50
Nasopharyngeal Swab 2	No		

US3292128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:46

PC Open Date & Time

08 SEP 2020 12:34

PC Close Date & Time

08 SEP 2020 15:04

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**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 98.5 °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	08 SEP 2020 17:15
PC Open Date & Time	08 SEP 2020 15:59
PC Close Date & Time	09 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 14:56

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 14:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:46

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:05

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 14:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**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

08 SEP 2020 12:47

PC Open Date & Time

08 SEP 2020 12:34

PC Close Date & Time

08 SEP 2020 15:04

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**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

08 SEP 2020 17:15

PC Open Date & Time

08 SEP 2020 15:59

PC Close Date & Time

09 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 14:56

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 14:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:47

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:05

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 14:22

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**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 ☐

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:47
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PC Open Date & Time	08 SEP 2020 12:34
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PC Close Date & Time	08 SEP 2020 15:04
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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**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 ☐

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:16
PC Open Date & Time	08 SEP 2020 15:59
PC Close Date & Time	09 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 14:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 14:28
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:48
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

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

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 14:23
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

15 SEP 2020 12:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

17 SEP 2020 12:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 06:09

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

20 SEP 2020 12:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:08

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 05:25

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 12:15

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

28 SEP 2020 06:02

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

28 SEP 2020 12:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 22

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

29 SEP 2020 12:06

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 23

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

30 SEP 2020 12:20

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 OCT 2020 14:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 25

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 26

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

04 OCT 2020 05:59

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 27

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 04 OCT 2020 12:00

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 28

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 12:12

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 29

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:43

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:36

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 31

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 08 OCT 2020 13:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 33

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 10 OCT 2020 12:24

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 34

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

11 OCT 2020 12:46

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 35

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 OCT 2020 12:32

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 36

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

13 OCT 2020 12:07

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

---



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 37

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

14 OCT 2020 12:01

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 38

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

15 OCT 2020 12:00

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 39

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 16 OCT 2020 12:01

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 40

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

18 OCT 2020 09:15

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 41

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 18 OCT 2020 12:00

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 42

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

19 OCT 2020 12:13

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 43

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

20 OCT 2020 12:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 44

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

21 OCT 2020 20:50

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

---



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 45

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 OCT 2020 12:00

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 46

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

23 OCT 2020 12:29

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 47

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 24 OCT 2020 12:10

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 48

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

26 OCT 2020 05:52

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 49

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 26 OCT 2020 12:12

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 50

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

27 OCT 2020 12:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 51

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 28 OCT 2020 12:04

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 52

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 OCT 2020 12:28

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 53

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

30 OCT 2020 14:03

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 54

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 OCT 2020 15:35

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 55

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 NOV 2020 12:32

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 56

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

02 NOV 2020 14:20

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 57

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

03 NOV 2020 12:08

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 58

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

04 NOV 2020 12:00

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 59

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

05 NOV 2020 12:23

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 60

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 NOV 2020 12:25

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 61

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

07 NOV 2020 12:06

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 62

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 NOV 2020 06:16

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 63

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

09 NOV 2020 12:21

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 64

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

10 NOV 2020 12:03

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 65

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

11 NOV 2020 12:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 66

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

12 NOV 2020 12:00

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 67

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 13 NOV 2020 12:38

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 68

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

14 NOV 2020 12:33

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

---



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 69

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

15 NOV 2020 12:00

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 70

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 16 NOV 2020 12:00

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 71

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

17 NOV 2020 17:33

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 72

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

18 NOV 2020 16:27

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 15 SEP 2020 12:17

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 16 SEP 2020 12:00

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

17 SEP 2020 12:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 19 SEP 2020 06:10

PC Open Date & Time 18 SEP 2020 12:00

---

PC Close Date & Time 19 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

19 SEP 2020 12:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

20 SEP 2020 12:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 21 SEP 2020 12:00

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

22 SEP 2020 12:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

24 SEP 2020 05:25

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**  
**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 24 SEP 2020 12:15

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 25 SEP 2020 12:01

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 12:00

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 28 SEP 2020 06:02

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 28 SEP 2020 12:03

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

29 SEP 2020 12:06

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

30 SEP 2020 12:20

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

01 OCT 2020 14:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

02 OCT 2020 12:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 26

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 OCT 2020 05:59

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 27

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 04 OCT 2020 12:00

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 OCT 2020 12:12

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 29

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 06 OCT 2020 12:43

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

07 OCT 2020 12:36

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 31

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 13:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 12:00

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 12:24

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 12:46

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 35

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 OCT 2020 12:32

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 36

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 12:07

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 37

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 12:01

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 38

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 OCT 2020 12:01

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 39

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 16 OCT 2020 12:01

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 40

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

18 OCT 2020 09:15

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 41

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 18 OCT 2020 12:00

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 42

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

19 OCT 2020 12:13

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 43

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

20 OCT 2020 12:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 44

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

21 OCT 2020 20:50

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 45

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 OCT 2020 12:00

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 46

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

23 OCT 2020 12:29

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 47

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

24 OCT 2020 12:11

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 48

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 OCT 2020 05:52

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 49

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 OCT 2020 12:13

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 50

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

27 OCT 2020 12:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 51

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 28 OCT 2020 12:04

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 52

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 29 OCT 2020 12:28

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 53

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

30 OCT 2020 14:03

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 54

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

31 OCT 2020 15:35

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 55

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

01 NOV 2020 12:32

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 56

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

02 NOV 2020 14:20

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 57

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

03 NOV 2020 12:08

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 58

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

04 NOV 2020 12:00

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 59

Select one response below to indicate the intensity of your **MUSCLE**  
**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 05 NOV 2020 12:23

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 60

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 NOV 2020 12:25

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 61

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

07 NOV 2020 12:06

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 62

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 NOV 2020 06:16

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 63

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 NOV 2020 12:21

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 64

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

10 NOV 2020 12:03

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 65

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 NOV 2020 12:00

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 66

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

12 NOV 2020 12:00

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 67

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 NOV 2020 12:38

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 68

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

14 NOV 2020 12:33

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 69

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 NOV 2020 12:00

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 70

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 NOV 2020 12:00

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 71

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 NOV 2020 17:33

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 72

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 NOV 2020 16:27

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 SEP 2020 12:17

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 SEP 2020 12:00

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PC Open Date & Time 16 SEP 2020 12:00

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PC Close Date & Time 17 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 17 SEP 2020 12:01

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 19 SEP 2020 06:10

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 19 SEP 2020 12:00

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 20 SEP 2020 12:00

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 21 SEP 2020 12:00

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

22 SEP 2020 12:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 SEP 2020 05:25

PC Open Date & Time 23 SEP 2020 12:00

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PC Close Date & Time 24 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 SEP 2020 12:15

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

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PC Time stamp	25 SEP 2020 12:01
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PC Open Date & Time	25 SEP 2020 12:00
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PC Close Date & Time	26 SEP 2020 11:59
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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 26 SEP 2020 12:00

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 28 SEP 2020 06:02

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 28 SEP 2020 12:03

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 22

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 29 SEP 2020 12:06

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 23

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 30 SEP 2020 12:20

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 24

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 01 OCT 2020 14:40

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 25

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 02 OCT 2020 12:04

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 26

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 04 OCT 2020 05:59

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

---



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 27

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 04 OCT 2020 12:00

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 28

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 05 OCT 2020 12:13

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 29

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 06 OCT 2020 12:44

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 30

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 07 OCT 2020 12:36

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 31

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 08 OCT 2020 13:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 32

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 OCT 2020 12:00

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 33

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 10 OCT 2020 12:24

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 11 OCT 2020 12:46

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 35

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 12 OCT 2020 12:32

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 36

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 13 OCT 2020 12:07

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 37

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 14 OCT 2020 12:01

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 38

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 OCT 2020 12:01

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 39

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 OCT 2020 12:01

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 40

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 18 OCT 2020 09:15

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 41

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 18 OCT 2020 12:00

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 42

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

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PC Time stamp 19 OCT 2020 12:13

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 43

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 20 OCT 2020 12:00

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 44

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

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PC Time stamp 21 OCT 2020 20:50

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 45

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 22 OCT 2020 12:00

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 46

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 23 OCT 2020 12:29

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 47

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 24 OCT 2020 12:11

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 48

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 26 OCT 2020 05:52

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 49

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 26 OCT 2020 12:13

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 50

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 27 OCT 2020 12:00

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 51

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 28 OCT 2020 12:04

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 52

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 29 OCT 2020 12:28

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 53

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 30 OCT 2020 14:03

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 54

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

31 OCT 2020 15:35

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 55

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

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PC Time stamp 01 NOV 2020 12:32

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 56

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

02 NOV 2020 14:20

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 57

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 03 NOV 2020 12:08

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

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**TIMEPOINT**

DAY 58

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 04 NOV 2020 12:00

PC Open Date & Time 04 NOV 2020 12:00

PC Close Date & Time 05 NOV 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 59

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 05 NOV 2020 12:23

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 60

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 06 NOV 2020 12:25

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 61

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 07 NOV 2020 12:06

PC Open Date & Time 07 NOV 2020 12:00

PC Close Date & Time 08 NOV 2020 11:59

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US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 62

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 09 NOV 2020 06:16

PC Open Date & Time 08 NOV 2020 12:00

PC Close Date & Time 09 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 63

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 NOV 2020 12:21

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 64

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 10 NOV 2020 12:03

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 65

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 11 NOV 2020 12:00

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 66

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 12 NOV 2020 12:00

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT

DAY 67

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 13 NOV 2020 12:38

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 68

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 14 NOV 2020 12:33

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 69

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 NOV 2020 12:00

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 70

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 NOV 2020 12:00

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 71

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 17 NOV 2020 17:33

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

---

**TIMEPOINT**

DAY 72

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 18 NOV 2020 16:28

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

---

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 12:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 12:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 06:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

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

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 12:00
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 12:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 12:09
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 16
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 05:25
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 17
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 12:15
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 18
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 19
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 12:00
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 20
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 06:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 21
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 12:03
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 22
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 12:06
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 23
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 12:20
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 24
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 14:40
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 25
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 12:04
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 26
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 05:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 27
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 12:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 28
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 12:13
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 29
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 12:44
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 30
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 12:36
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 31
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 13:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 32
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 12:01
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 33
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 12:24
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 34
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 12:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 35
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 OCT 2020 12:32
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 36
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 12:08
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 37
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 12:01
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 38
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 12:01
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 39
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 12:01
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 40
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 09:16
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 41
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 12:00
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 42
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 OCT 2020 12:13
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 43
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 12:00
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 44
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 20:50
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 45
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 12:01
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 46
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 12:29
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 47
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 12:11
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 48
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 05:53
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 49
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 12:13
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 50
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 12:00
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 51
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 12:04
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 52
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 OCT 2020 12:28
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 53
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 14:03
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 54
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 OCT 2020 15:35
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 55
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 NOV 2020 12:32
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 56
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 NOV 2020 14:20
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 57
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 NOV 2020 12:08
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 58
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 NOV 2020 12:01
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 59
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 NOV 2020 12:24
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 60
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 NOV 2020 12:25
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 61
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 NOV 2020 12:06
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 62
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 NOV 2020 06:17
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 63
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 NOV 2020 12:21
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 64
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 NOV 2020 12:03
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 65
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 12:00
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 66
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 NOV 2020 12:00
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 67
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 NOV 2020 12:38
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 68
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 NOV 2020 12:34
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 69
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 NOV 2020 12:00
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 70
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 NOV 2020 12:00
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 70
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 NOV 2020 12:01
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 71
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 NOV 2020 17:33
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 72
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 16:28
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59



US3292128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

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

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

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

CONTACT ATTEMPTED ONCE  
IN ERROR, CALL NOT  
CONDUCTED.

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

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

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 08:23
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3292128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

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.*

US3292128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	08:27 (24 HR)
Collection date and time (derived)	6 OCT 2020 08:27

US3292128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:56

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 OCT 2020 12:47:47
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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

18 OCT 2020 09:16:32

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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 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 OCT 2020 04:43:24
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 NOV 2020 05:40:58
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 03:47:07
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 06:58:19

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 04:42:17

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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

03 DEC 2020 05:01:02

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	10 DEC 2020 04:54:45
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:00:28

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 07:23:36

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 08:40:35

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 12:03:18

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 06:19:33

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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

21 JAN 2021 10:22:14

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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

28 JAN 2021 05:47:35

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	04 FEB 2021 05:26:03
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	11 FEB 2021 05:15:33
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	18 FEB 2021 05:15:24
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 11:50:49

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 00:22:53

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	13 MAR 2021 11:49:48
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 10:11:04

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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 <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 MAR 2021 05:57:25
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

<b>TIMEPOINT</b>	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	01 APR 2021 07:54:17
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 07:49:09

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

Date and time of submission

17 APR 2021 07:05:46

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

Date and time of submission

22 APR 2021 06:44:11

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 05:04:33

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

10 MAY 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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14 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 OCT 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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23 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 DEC 2021 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

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

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[Patient Cloud Open Date & Time](#)

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22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

DAY 782

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**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 ☐

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 OCT 2022 23:59

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US3292128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:22:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 13:54:27

US3292128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292128

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:15:38

Generated On: 09 Jun 2021 16:22:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:15:38

Generated On: 09 Jun 2021 16:22:59

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) \_\_\_\_\_

US3292128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:15:38

Generated On: 09 Jun 2021 16:22:59

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.*

US3292128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:15:38

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 MAR 2021
Collection time (00:00-23:59)	08:00 (24 HR)
Collection date and time (derived)	1 MAR 2021 08:00

US3292128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:15:38

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:03:13

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:03:13

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292128

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

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*

**US3292128**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292128

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:22:59

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3292128**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:22:59**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Date of updated informed consent (dd MMM yyyy)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 08:10
Temperature (xxx.x)	35.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:14
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

19 JAN 2021

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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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US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 09:44

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

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	08:27 (24 HR)
Collection date and time (derived)	19 JAN 2021 08:27

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	08:35
Collection Date and Time (derived)	19 JAN 2021 08:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:47:50

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3292128

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

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)	26 FEB 2021
Time of assessment (00:00-23:59)	07:35 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 07:35
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:16
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3292128

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3292128

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 08:45 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 08:45

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

US3292128

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:12:31

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292128

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

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) \_\_\_\_\_

US3292128

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

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.*

US3292128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

07:48 (24 HR)

Collection date and time (derived)

26 MAR 2021 07:48

US3292128

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 16:15:37

Generated On: 09 Jun 2021 16:22:59

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

AEID	USA-US072-2021-MRNA-1273-P30 1000016
Adverse event	DOG BITE R ARM
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)	03 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	4 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	5 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

---

SUBJECT STATED HE WAS  
ATTACKED BY A DOG ON  
03MAR2021, HE WAS BITTEN ON  
HIS R ARM BELOW THE ELBOW  
AND HAD TO BE ADMITTED TO  
BAMC ON 04MAR2021 DUE TO  
CONTINUOUS BLEEDING, THEY  
PERFORMED A PROCEDURE TO  
DEBRIDE THE WOUND AND  
PACK IT. HE IS PENDING TO BE  
DISCHARGED LATER.  
MEDICAL RECORDS WILL BE  
REQUESTED. AE LOG  
UPDATED.  
UNK PROCEDURE, PENDING  
MEDICAL RECORDS.

---

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

---



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

---

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication CENTRUM SILVER

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED GOUT

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2004
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication ATENOLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication CALC CARB + D

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 600/400

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify MG/IU

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication COLECALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☒  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☒  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	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)		12 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input checked="" type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication AMOXICILLIN/CLAVULANIC  
ACID

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

Dose per administration 500/125

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)

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US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	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)		5 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication DOCUSATE

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

Dose per administration 7.5/325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE R ARM

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:47:08

Generated On: 09 Jun 2021 16:22:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 18:47:49

Generated On: 09 Jun 2021 16:22:59

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3292128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:22:59

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

US3292128

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:59

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 ☐



US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

SAEID	USA-US072-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

SAEID	USA-US072-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

SAEID	USA-US072-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 09:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

SAEID	USA-US072-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 10:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 18:32:38

Generated On: 09 Jun 2021 16:22:59

SAEID	USA-US072-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 12:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292128 (Prod: Clinical Trials of Texas, Inc)

**US3292128**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:22:59**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	13 Jan 2021 20:03:42
User entered 'US3292128'	(b) (4), (b) (6)	11 Aug 2020 17:45:35
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

US3292128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:32:45



US3292128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:39:54
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:36

US3292128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:39:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Aug 2020 17:32:45

**US3292128**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:22:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'SCRN'	System	12 Aug 2020 17:32:45

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:40:19
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:37

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:19
User entered '74'	(b) (4), (b) (6)	12 Aug 2020 17:32:58

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'YEARS'	System	12 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '75'	System	11 Aug 2020 19:26:32

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:40:19
User entered 'Male (M)'		12 Aug 2020 17:32:58



US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:40:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		12 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:40:19
User entered 'l'		2 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:40:19
User entered '0'		12 Aug 2020 17:32:58

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:40:19
User entered '0'		12 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:40:19
User entered '0'		12 Aug 2020 17:32:58

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:19
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:32:58

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:40:19
User entered '0'		12 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:19
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:32:58



**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:40:19
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:32:58

**US3292128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:22:59**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:19
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:32:58

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:29
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:26:32

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Aug 2020'	System	11 Aug 2020 19:26:32

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	11 Aug 2020 19:26:32

**US3292128**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:22:59**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:29
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	11 Aug 2020 19:26:32

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:26:32

**US3292128**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:22:59**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:29
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:26:32



**US3292128**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:22:59**

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:40:29
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:26:32

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:40:29
User entered 'No (N)'		11 Aug 2020 19:26:32

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:40:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:36

US3292128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'l'	System	11 Aug 2020 19:26:38

**US3292128**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 16:22:59**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:41:12
User entered 'Yes (Y)'		11 Aug 2020 19:26:38

US3292128

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:22:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:33:04

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 17:34:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 17:34:20
Data point term sent to Coder	System	12 Aug 2020 17:33:42
User entered 'Environmental allergies'	(b) (4), (b) (6)	12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'un UNK 1987'		12 Aug 2020 17:33:18



US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:18

**US3292128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'		12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 1987'	System	12 Aug 2020 17:33:18

**US3292128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '1987'	System	12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:18

US3292128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:18



US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:34:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:34:19
Data point term sent to Coder	System	12 Aug 2020 17:33:42
User entered 'Vasectomy'	(b) (4), (b) (6)	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	7 Aug 2020 17:44:29
User entered 'un UNK 1972'	(b) (4), (b) (6)	2 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:33

**US3292128**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'		12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 1972'	System	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '1972'	System	12 Aug 2020 17:33:33



US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:33

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:36:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:16
Data point term sent to Coder	System	12 Aug 2020 17:34:44
User entered 'Decreased visual acuity'	(b) (4), (b) (6)	12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User closed query 'Source states 1990. Please review and clarify. ' (Site from CRA).	(b) (4)	19 Jan 2021 20:27:41
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:27:36
Query 'Source states 1990. Please review and clarify. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	27 Aug 2020 20:13:31
User entered 'UN UNK 1990' reason for change:	(b) (4)	27 Aug 2020 20:13:27
Data Entry Error	Dawn Killian (b) (4)	27 Aug 2020 20:13:27
DataPoint Un-verified.	(b) (4)	27 Aug 2020 17:44:39
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User opened query 'Source states 1990. Please review and clarify. ' (Site from CRA).		27 Aug 2020 17:42:14
User entered 'un UNK 1980'		12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:56

**US3292128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:33:56



**US3292128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 1990'	System	27 Aug 2020 20:13:27
User entered 'Jan 1980'	System	12 Aug 2020 17:33:56

**US3292128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '1990'	System	27 Aug 2020 20:13:27
User entered '1980'	System	12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:56

**US3292128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:33:56

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:16
Data point term sent to Coder	System	12 Aug 2020 17:34:44
User entered 'Hypertension'	(b) (4), (b) (6)	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'un UNK 1990'	(b) (4), (b) (6)	12 Aug 2020 17:34:08

**US3292128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:34:08

**US3292128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:34:08



US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 1990'	System	12 Aug 2020 17:34:08

**US3292128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '1990'	System	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:08

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:15
Data point term sent to Coder	System	12 Aug 2020 17:34:44
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	12 Aug 2020 17:34:20

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un UNK 1997'	(b) (4), (b) (6)	12 Aug 2020 17:34:20



US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:34:20

**US3292128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:34:20

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:34:20

**US3292128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered '0'		12 Aug 2020 17:34:20

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 1997'	System	12 Aug 2020 17:34:20

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '1997'	System	12 Aug 2020 17:34:20

**US3292128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:20

US3292128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:20



US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User closed query 'Please update Medical History source with updated condition' (Site from CRA). DataPoint Verified.	(b) (4)	19 Apr 2021 17:00:30
	(b) (4)	19 Apr 2021 17:00:28
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
	(b) (4)	
Query 'Please update Medical History source with updated condition' answered with 'source updated' (Site from CRA).	Antonio Gutierrez (b) (4)	01 Apr 2021 21:05:24
	(b) (4)	
User opened query 'Please update Medical History source with updated condition' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:10:58
User closed query 'Per DM CLR: Please specify the location of Gout. Update Med History eCRF as appropriate.	(b) (4)	08 Oct 2020 10:28:37
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 16:04:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 16:04:48
Data point term sent to Coder	System	24 Sep 2020 16:04:07
Query 'Per DM CLR: Please specify the location of Gout. Update Med History eCRF as appropriate.	Dawn Killian (b) (4)	24 Sep 2020 16:03:31
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Dawn Killian (b) (4)	24 Sep 2020 16:03:27
	(b) (4)	
Coding entries removed.	Dawn Killian (b) (4)	24 Sep 2020 16:03:27
	(b) (4)	
User entered 'generalized GOUT' reason for change: Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 16:03:27
	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of Gout. Update Med History eCRF as appropriate.	(b) (4), (b) (6)	22 Sep 2020 09:42:39
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:36:16
Data point term sent to Coder	System	12 Aug 2020 17:34:44
User entered 'Gout'	(b) (4), (b) (6)	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un UNK 2004'	(b) (4), (b) (6)	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:34:31

**US3292128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Jan 2004'	System	12 Aug 2020 17:34:31



**US3292128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2004'	System	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	12 Aug 2020 17:34:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:48:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:48:19
Data point term sent to Coder	System	12 Aug 2020 17:40:53
User entered 'R rotator cuff surgery'	(b) (4), (b) (6)	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2017'	(b) (4), (b) (6)	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'un May 2017'		12 Aug 2020 17:40:31



**US3292128**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:22:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2017'	System	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2017'	System	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2017'	System	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2017'	System	12 Aug 2020 17:40:31

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:46:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:46:20
Data point term sent to Coder	System	12 Aug 2020 17:41:54
User entered 'L rotator cuff repair'	(b) (4), (b) (6)	12 Aug 2020 17:40:57

**US3292128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered 'un May 2020'		12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:40:57



US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:40:57

**US3292128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:22:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2020'	(b) (4), (b) (6)	12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2020'	System	12 Aug 2020 17:40:57

**US3292128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2020'	System	12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	12 Aug 2020 17:40:57

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:29:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:29:19
Data point term sent to Coder	System	17 Aug 2020 18:27:27
User entered 'Right torn rotator cuff'	(b) (4), (b) (6)	17 Aug 2020 18:27:13



US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2017'	(b) (4), (b) (6)	17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 18:27:13

**US3292128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:22:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 18:27:13

**US3292128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:22:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2017'	(b) (4), (b) (6)	17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:44:29
User entered '0'		17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2017'	System	17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2017'	System	17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2017'	System	17 Aug 2020 18:27:13



**US3292128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:22:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2017'	System	17 Aug 2020 18:27:13

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:44:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:29:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 18:29:50
Data point term sent to Coder	System	17 Aug 2020 18:28:28
User entered 'Left torn rotator cuff'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2020'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered 'un May 2020'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4)	27 Aug 2020 17:44:29
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2020'	System	17 Aug 2020 18:27:37



US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'May 2020'	System	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	17 Aug 2020 18:27:37

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User closed query 'Please provide source' (Site from CRA).	(b) (4)	19 Apr 2021 17:03:02
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:38
Query 'Please provide source' answered with 'MedHx source updated' (Site from CRA).	Antonio Gutierrez (b) (4)	01 Apr 2021 21:08:37
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:11:50
User opened query 'Please provide source' (Site from CRA).	(b) (4)	08 Feb 2021 16:21:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:09:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:09:57
Data point term sent to Coder	System	24 Sep 2020 16:09:29
User entered 'vitamin D deficiency'	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:11:55
User entered '12 Feb 2020'	Dawn Killian (b) (4)	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:11:58
User entered '0'	Dawn Killian (b) (4)	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:12:03
User entered 'Yes (Y)'	Dawn Killian (b) (4)	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:12:05
User entered empty.	Dawn Killian (b) (4)	24 Sep 2020 16:08:33



US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:12:07
User entered '0'	Dawn Killian (b) (4)	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'Feb 2020'	System	24 Sep 2020 16:08:33

**US3292128**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:22:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '2020'	System	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered empty.	System	24 Sep 2020 16:08:33

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User entered 'Yes (Y)'		12 Aug 2020 17:41:37

**US3292128**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:51:36
User entered '11 Aug 2020'		12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:19
User entered '12:45' reason for change: Data Entry Error		14 Aug 2020 17:51:49
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:16
User opened query 'Data is required. Please provide.' (Site from System).		12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37



US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered '11 Aug 2020 12:45'	System	14 Aug 2020 17:51:49
User entered empty.	System	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User entered '172.0' cm		12 Aug 2020 17:41:37
DataPoint set to visible.	System	11 Aug 2020 19:26:38

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User entered '104.7' kg		12 Aug 2020 17:41:37
DataPoint set to visible.	System	11 Aug 2020 19:26:38

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
Amendment Manager: User entered '35.39075'	System	16 Sep 2020 23:52:00
User entered '35.4'	System	12 Aug 2020 17:41:37
DataPoint set to visible.	System	11 Aug 2020 19:26:38

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'kg/m2'	System	12 Aug 2020 17:41:37
DataPoint set to visible.	System	11 Aug 2020 19:26:38

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:21
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:59:53
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:18
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:27
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:21
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:51:36
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37



US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:29
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:59:53
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:23
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

**US3292128**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'bpm'	System	14 Aug 2020 01:59:53
User entered empty.	System	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:31
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:59:53
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:26
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'breaths/min'	System	14 Aug 2020 01:59:53
User entered empty.	System	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:33
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:59:53
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:29
User opened query 'Data is required. Please provide.' System (Site from System).		12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'mmHg'	System	14 Aug 2020 01:59:53
User entered empty.	System	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:36
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:08:37
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:59:53
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).		12 Aug 2020 17:42:31
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:41:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:41:37

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User entered 'mmHg'	System	14 Aug 2020 01:59:53
User entered empty.	System	12 Aug 2020 17:41:37



US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25

US3292128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25

US3292128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:51:56
User entered 'Yes (Y)' reason for change: Data Entry Error		14 Aug 2020 02:00:10
User entered 'No (N)'		12 Aug 2020 17:42:35

US3292128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:27:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:51:56
User entered '11 Aug 2020' reason for change: Data Entry Error		14 Aug 2020 02:00:10
User entered empty.		12 Aug 2020 17:42:35

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31



US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:52:16
User entered 'No (N)'		12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:52:16
User entered 'Yes (Y)'		12 Aug 2020 17:43:31



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered 'Shopping (grocery, retail) 2+ times per week, wife is personal caretaker for another patient'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:52:16
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

**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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

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 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:16
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:52:16
User entered 'l'		12 Aug 2020 17:43:31

US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:43:31



US3292128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 17:52:16
User entered empty.		12 Aug 2020 17:43:31

US3292128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:44:13

US3292128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:29
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 17:44:13

US3292128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:52:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Aug 2020 17:44:13

**US3292128**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:22:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'VISIT1'	System	12 Aug 2020 17:44:13

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:59:02
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:59:22

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:59:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:37:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:37:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:59:22
User entered '185731' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:59:22

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:59:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:59:22



US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

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)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:59:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:44:27

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

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)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:59:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:44:27

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:59:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:44:27

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:59:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:44:27

US3292128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 17:59:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:44:27

**US3292128**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:22:59**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:33:30

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:46:05



US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Pre-Dose (PREDOSE)'		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:00:41
User entered '12:45'		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '11 Aug 2020 12:45'	System	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '36.5' C	(b) (4), (b) (6)	12 Aug 2020 17:46:05



US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '67'	(b) (4), (b) (6)	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'bpm'	System	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:00:41
User entered '16'		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'breaths/min'	System	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:00:41
User entered '139'		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	12 Aug 2020 17:46:05



US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:00:41
User entered '80'		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:09
User entered empty.		12 Aug 2020 17:46:05

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Post-Dose (POSTDOSE)'		12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:00:41
User entered 'Yes (Y)'		12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:00:41
User entered '11 Aug 2020'		12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	7 Aug 2020 18:00:41
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	4 Aug 2020 15:15:16
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can occur 30 minutes post dose' (Site from System).		2 Aug 2020 17:47:15
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 17:46:56
User entered '15:00'	(b) (4), (b) (6)	12 Aug 2020 17:46:56



US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '11 Aug 2020 15:00'	System	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '36.7' C	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:00:41
User entered 'Oral (Oral)'		12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '64'	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'bpm'	System	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '16'	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'breaths/min'	System	12 Aug 2020 17:46:56



US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '120'	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:41
User entered '74'	(b) (4), (b) (6)	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	12 Aug 2020 17:46:56

US3292128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:24
User entered 'Yes (Y)'		12 Aug 2020 17:47:26

US3292128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:00:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:59:24
User entered '11 Aug 2020'		12 Aug 2020 17:47:26

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:27:07



US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

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)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered '14:22'	(b) (4), (b) (6)	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '11 Aug 2020 14:22'	System	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:06
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:01:06
User entered 'ONCE'	System	11 Aug 2020 19:27:07

US3292128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:27:07



US3292128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:47:37

US3292128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:16
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 17:47:37

US3292128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:16
User entered '13:34'	(b) (4), (b) (6)	12 Aug 2020 17:47:37

US3292128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '11 Aug 2020 13:34'	System	12 Aug 2020 17:47:37

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:22:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:01:22
User entered '11 Aug 2020'		12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:22
User entered '13:48'	(b) (4), (b) (6)	12 Aug 2020 17:47:46



US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '11 Aug 2020 13:48'	System	12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:01:22
User entered 'No (N)'		12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:22
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered empty.	System	12 Aug 2020 17:47:46

US3292128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 27 Aug 2020 18:01:27
User entered 'Yes (Y)'		12 Aug 2020 17:47:53

US3292128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'I'	System	12 Aug 2020 17:47:53

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:01:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78802e70-eb67-473d-bd3e-38ea1a624c7d' User entered 'Yes (Y)'	System	11 Aug 2020 20:02:17
	System	11 Aug 2020 20:02:17

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:01:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78802e70-eb67-473d-bd3e-38ea1a624c7d' User entered '98.1'	System	11 Aug 2020 20:02:17
	System	11 Aug 2020 20:02:17

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:02:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78802e70-eb67-473d-bd3e-38ea1a624c7d' User entered 'No (N)'	System	11 Aug 2020 20:02:17
	System	11 Aug 2020 20:02:17

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:02:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78802e70-eb67-473d-bd3e-38ea1a624c7d' User entered '11 Aug 2020 15:02'	System	11 Aug 2020 20:02:17
	System	11 Aug 2020 20:02:17

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 14:42'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 17:12'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:08:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2f8cdc-0648-4176-bbf8-81709f4b40a3'	System	11 Aug 2020 23:09:25
User entered 'Yes (Y)'	System	11 Aug 2020 23:09:25



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2f8cdc-0648-4176-bbf8-81709f4b40a3' User entered '97.6'	System	11 Aug 2020 23:09:25
	System	11 Aug 2020 23:09:25

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2f8cdc-0648-4176-bbf8-81709f4b40a3'	System	11 Aug 2020 23:09:25
User entered 'No (N)'	System	11 Aug 2020 23:09:25

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2f8cdc-0648-4176-bbf8-81709f4b40a3'	System	11 Aug 2020 23:09:25
User entered '11 Aug 2020 18:09'	System	11 Aug 2020 23:09:25

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 18:07'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 2'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:56:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '66c5a1cb-41f8-4538-adc5-8ac083b8c8b3' User entered 'Yes (Y)'	System	12 Aug 2020 18:57:11
	System	12 Aug 2020 18:57:11

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:56:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '66c5a1cb-41f8-4538-adc5-8ac083b8c8b3' User entered '97.8'	System	12 Aug 2020 18:57:11
	System	12 Aug 2020 18:57:11



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '66c5a1cb-41f8-4538-adc5-8ac083b8c8b3'	System	12 Aug 2020 18:57:11
User entered 'No (N)'	System	12 Aug 2020 18:57:11

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '66c5a1cb-41f8-4538-adc5-8ac083b8c8b3'	System	12 Aug 2020 18:57:11
User entered '12 Aug 2020 13:57'	System	12 Aug 2020 18:57:11

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 3'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:31:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '153e3a2d-a8df-491e-86c6-78b0b219e3cd' User entered 'Yes (Y)'	System	13 Aug 2020 17:31:46
	System	13 Aug 2020 17:31:46

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:31:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '153e3a2d-a8df-491e-86c6-78b0b219e3cd' User entered '96.7'	System	13 Aug 2020 17:31:46
	System	13 Aug 2020 17:31:46

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:31:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '153e3a2d-a8df-491e-86c6-78b0b219e3cd'	System	13 Aug 2020 17:31:46
User entered 'No (N)'	System	13 Aug 2020 17:31:46



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:31:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '153e3a2d-a8df-491e-86c6-78b0b219e3cd' User entered '13 Aug 2020 12:31'	System	13 Aug 2020 17:31:46
	System	13 Aug 2020 17:31:46

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 4'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:20:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468448d2-4202-4c9a-8c55-e32789ce85b1' User entered 'Yes (Y)'	System	14 Aug 2020 17:23:56
	System	14 Aug 2020 17:23:56

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:23:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468448d2-4202-4c9a-8c55-e32789ce85b1' User entered '97.0'	System	14 Aug 2020 17:23:56
	System	14 Aug 2020 17:23:56

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:23:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468448d2-4202-4c9a-8c55-e32789ce85b1'	System	14 Aug 2020 17:23:56
User entered 'No (N)'	System	14 Aug 2020 17:23:56

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:23:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468448d2-4202-4c9a-8c55-e32789ce85b1' User entered '14 Aug 2020 12:23'	System	14 Aug 2020 17:23:56
	System	14 Aug 2020 17:23:56



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 5'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0abfe641-3a38-481c-afef-d6c24a952492'	System	15 Aug 2020 19:35:33
User entered 'Yes (Y)'	System	15 Aug 2020 19:35:33

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0abfe641-3a38-481c-afef-d6c24a952492' User entered '97.4'	System	15 Aug 2020 19:35:33
	System	15 Aug 2020 19:35:33

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0abfe641-3a38-481c-afef-d6c24a952492'	System	15 Aug 2020 19:35:33
User entered 'No (N)'	System	15 Aug 2020 19:35:33

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0abfe641-3a38-481c-afef-d6c24a952492'	System	15 Aug 2020 19:35:33
User entered '15 Aug 2020 14:35'	System	15 Aug 2020 19:35:33

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 6'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:08:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b4507c6c-dca0-485f-aff7-df20fd904811' User entered 'Yes (Y)'	System	16 Aug 2020 17:09:23
	System	16 Aug 2020 17:09:23

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b4507c6c-dca0-485f-aff7-df20fd904811' User entered '97.9'	System	16 Aug 2020 17:09:23
	System	16 Aug 2020 17:09:23

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b4507c6c-dca0-485f-aff7-df20fd904811'	System	16 Aug 2020 17:09:23
User entered 'No (N)'	System	16 Aug 2020 17:09:23

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b4507c6c-dca0-485f-aff7-df20fd904811' User entered '16 Aug 2020 12:09'	System	16 Aug 2020 17:09:23
	System	16 Aug 2020 17:09:23

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 7'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f26b0dcb-b706-4463-9648-73232266afee' User entered 'Yes (Y)'	System	17 Aug 2020 17:35:28
	System	17 Aug 2020 17:35:28

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f26b0dcb-b706-4463-9648-73232266afee' User entered '98.3'	System	17 Aug 2020 17:35:28
	System	17 Aug 2020 17:35:28

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f26b0dcb-b706-4463-9648-73232266afee'	System	17 Aug 2020 17:35:28
User entered 'No (N)'	System	17 Aug 2020 17:35:28

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f26b0dcb-b706-4463-9648-73232266afee' User entered '17 Aug 2020 12:35'	System	17 Aug 2020 17:35:28
	System	17 Aug 2020 17:35:28

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:02:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '183d3dec-89f8-4d8b-9f22-5a70b4c01f18'	System	11 Aug 2020 20:03:17
User entered 'None (1)'	System	11 Aug 2020 20:03:17

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '183d3dec-89f8-4d8b-9f22-5a70b4c01f18'	System	11 Aug 2020 20:03:17
User entered 'No (N)'	System	11 Aug 2020 20:03:17

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '183d3dec-89f8-4d8b-9f22-5a70b4c01f18'	System	11 Aug 2020 20:03:17
User entered 'No (N)'	System	11 Aug 2020 20:03:17

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '183d3dec-89f8-4d8b-9f22-5a70b4c01f18'	System	11 Aug 2020 20:03:17
User entered 'None (1)'	System	11 Aug 2020 20:03:17

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '183d3dec-89f8-4d8b-9f22-5a70b4c01f18'	System	11 Aug 2020 20:03:17
User entered '11 Aug 2020 15:03'	System	11 Aug 2020 20:03:17

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 14:42'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 17:12'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '972a1919-4005-49e0-8d11-094e4645b43c'	System	11 Aug 2020 23:09:50
User entered 'None (1)'	System	11 Aug 2020 23:09:50

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '972a1919-4005-49e0-8d11-094e4645b43c' User entered 'No (N)'	System	11 Aug 2020 23:09:50
	System	11 Aug 2020 23:09:50

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '972a1919-4005-49e0-8d11-094e4645b43c' User entered 'No (N)'	System	11 Aug 2020 23:09:50
	System	11 Aug 2020 23:09:50

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:45', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '972a1919-4005-49e0-8d11-094e4645b43c' User entered 'None (1)'	System	11 Aug 2020 23:09:50
	System	11 Aug 2020 23:09:50

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:09:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '972a1919-4005-49e0-8d11-094e4645b43c' User entered '11 Aug 2020 18:09'	System	11 Aug 2020 23:09:50
	System	11 Aug 2020 23:09:50

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 18:07'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 2'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4c2dec0c-8781-47de-bda2-1cd41cb60153'	System	12 Aug 2020 18:57:42
User entered 'None (1)'	System	12 Aug 2020 18:57:42

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4c2dec0c-8781-47de-bda2-1cd41cb60153'	System	12 Aug 2020 18:57:42
User entered 'No (N)'	System	12 Aug 2020 18:57:42

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4c2dec0c-8781-47de-bda2-1cd41cb60153'	System	12 Aug 2020 18:57:42
User entered 'No (N)'	System	12 Aug 2020 18:57:42

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4c2dec0c-8781-47de-bda2-1cd41cb60153'	System	12 Aug 2020 18:57:42
User entered 'None (1)'	System	12 Aug 2020 18:57:42

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4c2dec0c-8781-47de-bda2-1cd41cb60153'	System	12 Aug 2020 18:57:42
User entered '12 Aug 2020 13:57'	System	12 Aug 2020 18:57:42

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 3'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f5f7cad-207c-49f6-b5e8-55da8c481682'	System	13 Aug 2020 17:32:49
User entered 'None (1)'	System	13 Aug 2020 17:32:49

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f5f7cad-207c-49f6-b5e8-55da8c481682'	System	13 Aug 2020 17:32:49
User entered 'No (N)'	System	13 Aug 2020 17:32:49

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f5f7cad-207c-49f6-b5e8-55da8c481682'	System	13 Aug 2020 17:32:49
User entered 'No (N)'	System	13 Aug 2020 17:32:49

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f5f7cad-207c-49f6-b5e8-55da8c481682'	System	13 Aug 2020 17:32:49
User entered 'None (1)'	System	13 Aug 2020 17:32:49

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f5f7cad-207c-49f6-b5e8-55da8c481682'	System	13 Aug 2020 17:32:49
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 17:32:49

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 4'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:24:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '137b0e1e-29ff-48f4-a7fe-58af7147d7ec'	System	14 Aug 2020 17:24:35
User entered 'None (1)'	System	14 Aug 2020 17:24:35

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:24:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '137b0e1e-29ff-48f4-a7fe-58af7147d7ec'	System	14 Aug 2020 17:24:35
User entered 'No (N)'	System	14 Aug 2020 17:24:35

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:24:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '137b0e1e-29ff-48f4-a7fe-58af7147d7ec'	System	14 Aug 2020 17:24:35
User entered 'No (N)'	System	14 Aug 2020 17:24:35

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:24:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '137b0e1e-29ff-48f4-a7fe-58af7147d7ec'	System	14 Aug 2020 17:24:35
User entered 'None (1)'	System	14 Aug 2020 17:24:35

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:24:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '137b0e1e-29ff-48f4-a7fe-58af7147d7ec'	System	14 Aug 2020 17:24:35
User entered '14 Aug 2020 12:24'	System	14 Aug 2020 17:24:35

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 5'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '501e2885-3637-4a95-80ee-8ad8c73ad224'	System	15 Aug 2020 19:36:01
User entered 'None (1)'	System	15 Aug 2020 19:36:01

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '501e2885-3637-4a95-80ee-8ad8c73ad224'	System	15 Aug 2020 19:36:01
User entered 'No (N)'	System	15 Aug 2020 19:36:01

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '501e2885-3637-4a95-80ee-8ad8c73ad224'	System	15 Aug 2020 19:36:01
User entered 'No (N)'	System	15 Aug 2020 19:36:01

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '501e2885-3637-4a95-80ee-8ad8c73ad224' User entered 'None (1)'	System	15 Aug 2020 19:36:01
	System	15 Aug 2020 19:36:01

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:35:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '501e2885-3637-4a95-80ee-8ad8c73ad224' User entered '15 Aug 2020 14:35'	System	15 Aug 2020 19:36:01
	System	15 Aug 2020 19:36:01

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 6'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e36ddba-552d-47de-8824-371e2dd4d978'	System	16 Aug 2020 17:09:40
User entered 'None (1)'	System	16 Aug 2020 17:09:40

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e36ddba-552d-47de-8824-371e2dd4d978'	System	16 Aug 2020 17:09:40
User entered 'No (N)'	System	16 Aug 2020 17:09:40

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e36ddba-552d-47de-8824-371e2dd4d978'	System	16 Aug 2020 17:09:40
User entered 'No (N)'	System	16 Aug 2020 17:09:40

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e36ddba-552d-47de-8824-371e2dd4d978'	System	16 Aug 2020 17:09:40
User entered 'None (1)'	System	16 Aug 2020 17:09:40

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e36ddba-552d-47de-8824-371e2dd4d978'	System	16 Aug 2020 17:09:40
User entered '16 Aug 2020 12:09'	System	16 Aug 2020 17:09:40

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 7'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3e48fa0c-50a9-499d-a4e8-9525d576a02c' User entered 'None (1)'	System	17 Aug 2020 17:35:48
	System	17 Aug 2020 17:35:48

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3e48fa0c-50a9-499d-a4e8-9525d576a02c' User entered 'No (N)'	System	17 Aug 2020 17:35:48
	System	17 Aug 2020 17:35:48

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3e48fa0c-50a9-499d-a4e8-9525d576a02c' User entered 'No (N)'	System	17 Aug 2020 17:35:48
	System	17 Aug 2020 17:35:48

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3e48fa0c-50a9-499d-a4e8-9525d576a02c' User entered 'None (1)'	System	17 Aug 2020 17:35:48
	System	17 Aug 2020 17:35:48

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3e48fa0c-50a9-499d-a4e8-9525d576a02c' User entered '17 Aug 2020 12:35'	System	17 Aug 2020 17:35:48
	System	17 Aug 2020 17:35:48

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612'	System	11 Aug 2020 20:03:52
User entered 'None (0)'	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612'	System	11 Aug 2020 20:03:52
User entered 'None (0)'	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612' User entered 'None (0)'	System	11 Aug 2020 20:03:52
	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612' User entered 'None (0)'	System	11 Aug 2020 20:03:52
	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612' User entered 'None (0)'	System	11 Aug 2020 20:03:52
	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612'	System	11 Aug 2020 20:03:52
User entered 'None (0)'	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612'	System	11 Aug 2020 20:03:52
User entered 'No (N)'	System	11 Aug 2020 20:03:52

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T15:03:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e11d642d-a916-479d-ad1b-01d747941612' User entered '11 Aug 2020 15:03'	System	11 Aug 2020 20:03:52
	System	11 Aug 2020 20:03:52



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 14:42'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 17:12'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'None (0)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291'	System	11 Aug 2020 23:11:03
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'None (0)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'None (0)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'None (0)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'None (0)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291' User entered 'No (N)'	System	11 Aug 2020 23:11:03
	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-11T18:10:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '584b2c18-7df6-4d97-a813-9e81ce6f6291'	System	11 Aug 2020 23:11:03
User entered '11 Aug 2020 18:10'	System	11 Aug 2020 23:11:03

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Aug 2020 18:07'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 2'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86' User entered 'None (0)'	System	12 Aug 2020 18:58:37
	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:57:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86'	System	12 Aug 2020 18:58:37
User entered 'No interference with activity (1)'	System	12 Aug 2020 18:58:37



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86'	System	12 Aug 2020 18:58:37
User entered 'No interference with activity (1)'	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86'	System	12 Aug 2020 18:58:37
User entered 'No interference with activity (1)'	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86' User entered 'None (0)'	System	12 Aug 2020 18:58:37
	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86' User entered 'None (0)'	System	12 Aug 2020 18:58:37
	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86'	System	12 Aug 2020 18:58:37
User entered 'No (N)'	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-12T13:58:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '284fda20-6659-474a-97d8-0c2184d71d86' User entered '12 Aug 2020 13:58'	System	12 Aug 2020 18:58:37
	System	12 Aug 2020 18:58:37

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 3'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:32:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'None (0)'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2' User entered 'None (0)'	System	13 Aug 2020 17:33:27
	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'None (0)'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered 'No (N)'	System	13 Aug 2020 17:33:27



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-13T12:33:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b3141a1-ffbe-4d8d-8e20-659aca1c16a2'	System	13 Aug 2020 17:33:27
User entered '13 Aug 2020 12:33'	System	13 Aug 2020 17:33:27

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 4'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered 'No interference with activity (1)'	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered 'No interference with activity (1)'	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered 'No interference with activity (1)'	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered 'No interference with activity (1)'	System	14 Aug 2020 17:25:41



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5' User entered 'None (0)'	System	14 Aug 2020 17:25:41
	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5' User entered 'None (0)'	System	14 Aug 2020 17:25:41
	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered 'No (N)'	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-14T12:25:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b9c3b3-3361-4e7a-9a62-b31d5e03f4f5'	System	14 Aug 2020 17:25:41
User entered '14 Aug 2020 12:25'	System	14 Aug 2020 17:25:41

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 5'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc' User entered 'None (0)'	System	15 Aug 2020 19:36:42
	System	15 Aug 2020 19:36:42



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc'	System	15 Aug 2020 19:36:42
User entered 'No interference with activity (1)'	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc'	System	15 Aug 2020 19:36:42
User entered 'No interference with activity (1)'	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc'	System	15 Aug 2020 19:36:42
User entered 'No interference with activity (1)'	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc' User entered 'None (0)'	System	15 Aug 2020 19:36:42
	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc' User entered 'None (0)'	System	15 Aug 2020 19:36:42
	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc' User entered 'No (N)'	System	15 Aug 2020 19:36:42
	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-15T14:36:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '956f5b0f-fc82-428a-baee-da28d5ce0edc' User entered '15 Aug 2020 14:36'	System	15 Aug 2020 19:36:42
	System	15 Aug 2020 19:36:42

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:27:07



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 6'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'None (0)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'No interference with activity (1)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:09:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'No interference with activity (1)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:10:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'No interference with activity (1)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:10:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'None (0)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:10:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'None (0)'	System	16 Aug 2020 17:10:19



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:10:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered 'No (N)'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-16T12:10:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfdc6ec0-49f6-4207-9633-7a582053cf94'	System	16 Aug 2020 17:10:19
User entered '16 Aug 2020 12:10'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 7'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered 'None (0)'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:35:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:36:26



US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9' User entered 'None (0)'	System	17 Aug 2020 17:36:26
	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9' User entered 'None (0)'	System	17 Aug 2020 17:36:26
	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered 'No (N)'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-17T12:36:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4707e3df-ce05-41bd-81a0-01348d8bd0c9'	System	17 Aug 2020 17:36:26
User entered '17 Aug 2020 12:36'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Aug 2020 17:10:19
User entered 'Day 8'	System	16 Aug 2020 17:10:19



US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:05:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '64707c4c-d1fe-466e-82bc-f9e1011e999f' User entered 'No interference with activity (1)'	System	18 Aug 2020 17:05:56
	System	18 Aug 2020 17:05:56

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:05:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '64707c4c-d1fe-466e-82bc-f9e1011e999f' User entered '18 Aug 2020 12:05'	System	18 Aug 2020 17:05:56
	System	18 Aug 2020 17:05:56

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Aug 2020 17:36:26
User entered 'Day 9'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5f474d7a-d8a5-47c3-a29e-154f18aaad71'	System	19 Aug 2020 17:13:09
User entered 'None (0)'	System	19 Aug 2020 17:13:09

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5f474d7a-d8a5-47c3-a29e-154f18aaad71'	System	19 Aug 2020 17:13:09
User entered '19 Aug 2020 12:13'	System	19 Aug 2020 17:13:09

US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:36:26



US3292128

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Aug 2020 17:10:19
User entered 'Day 8'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bc86130d-40d1-4b59-b174-81c6ee1932cc'	System	18 Aug 2020 17:06:09
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:06:09

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bc86130d-40d1-4b59-b174-81c6ee1932cc' User entered '18 Aug 2020 12:06'	System	18 Aug 2020 17:06:09
	System	18 Aug 2020 17:06:09

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Aug 2020 17:36:26
User entered 'Day 9'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2cc758b8-3a1f-458e-ae6e-af394a70c783'	System	19 Aug 2020 17:13:23
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:13:23



US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2cc758b8-3a1f-458e-ae6e-af394a70c783'	System	19 Aug 2020 17:13:23
User entered '19 Aug 2020 12:13'	System	19 Aug 2020 17:13:23

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Aug 2020 17:06:09
User entered 'Day 10'	System	18 Aug 2020 17:06:09

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c880e706-a3c1-42b2-a039-91ba7f285629' User entered 'None (0)'	System	21 Aug 2020 11:01:31
	System	21 Aug 2020 11:01:31

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c880e706-a3c1-42b2-a039-91ba7f285629'	System	21 Aug 2020 11:01:31
User entered '21 Aug 2020 06:01'	System	21 Aug 2020 11:01:31

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:06:09

US3292128

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:06:09



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Aug 2020 17:10:19
User entered 'Day 8'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '18e1dfdb-f418-439f-b39a-22c0762f75eb' User entered 'No interference with activity (1)'	System	18 Aug 2020 17:06:20
	System	18 Aug 2020 17:06:20

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '18e1dfdb-f418-439f-b39a-22c0762f75eb' User entered '18 Aug 2020 12:06'	System	18 Aug 2020 17:06:20
	System	18 Aug 2020 17:06:20

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Aug 2020 17:36:26
User entered 'Day 9'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e5d81d9-e19b-423c-b84e-2660764c4b11'	System	19 Aug 2020 17:13:33
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:13:33

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e5d81d9-e19b-423c-b84e-2660764c4b11'	System	19 Aug 2020 17:13:33
User entered '19 Aug 2020 12:13'	System	19 Aug 2020 17:13:33



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Aug 2020 17:06:20
User entered 'Day 10'	System	18 Aug 2020 17:06:20

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a5bdf986-41b2-452e-ba79-be1eaf0513c6'	System	21 Aug 2020 11:01:44
User entered 'No interference with activity (1)'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a5bdf986-41b2-452e-ba79-be1eaf0513c6' User entered '21 Aug 2020 06:01'	System	21 Aug 2020 11:01:44
	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:06:20

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:06:20

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Aug 2020 17:13:33
User entered 'Day 11'	System	19 Aug 2020 17:13:33



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T06:00:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '98811ee1-c726-49b3-9ee5-667a86235efd'	System	22 Aug 2020 11:00:46
User entered 'No interference with activity (1)'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T06:00:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '98811ee1-c726-49b3-9ee5-667a86235efd' User entered '22 Aug 2020 06:00'	System	22 Aug 2020 11:00:46
	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:13:33

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:13:33

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Aug 2020 11:01:44
User entered 'Day 12'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T23:59:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '19e6870a-1408-4d12-bb83-25c970cbfd54'	System	23 Aug 2020 05:00:04
User entered 'No interference with activity (1)'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T23:59:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '19e6870a-1408-4d12-bb83-25c970cbfd54' User entered '22 Aug 2020 23:59'	System	23 Aug 2020 05:00:04
	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 11:01:44



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Aug 2020 11:00:46
User entered 'Day 13'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T13:19:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e8291c72-5972-4059-be41-81828cf3285f' User entered 'No interference with activity (1)'	System	23 Aug 2020 18:19:30
	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T13:19:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e8291c72-5972-4059-be41-81828cf3285f' User entered '23 Aug 2020 13:19'	System	23 Aug 2020 18:19:30
	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Aug 2020 05:00:04
User entered 'Day 14'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-24T12:12:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8d13f0d1-75c8-48e1-8b7a-6cb3e96ee67d'	System	24 Aug 2020 17:12:23
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:12:23



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-24T12:12:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8d13f0d1-75c8-48e1-8b7a-6cb3e96ee67d' User entered '24 Aug 2020 12:12'	System	24 Aug 2020 17:12:23
	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Aug 2020 18:19:30
User entered 'Day 15'	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-25T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b88ba0-d640-40b1-8eb3-04e06e1643a3'	System	25 Aug 2020 17:00:30
User entered 'No interference with activity (1)'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-25T12:00:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8b88ba0-d640-40b1-8eb3-04e06e1643a3' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:30
	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 18:19:30



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Aug 2020 17:12:23
User entered 'Day 16'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-26T19:07:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b86faeae-72dd-492d-b2ed-2ce9f361d9ad'	System	27 Aug 2020 00:07:15
User entered 'No interference with activity (1)'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-26T19:07:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b86faeae-72dd-492d-b2ed-2ce9f361d9ad'	System	27 Aug 2020 00:07:15
User entered '26 Aug 2020 19:07'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Aug 2020 17:00:30
User entered 'Day 17'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-27T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '85ba445a-6c18-45a6-ad17-476754408cf8'	System	27 Aug 2020 17:00:30
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-27T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '85ba445a-6c18-45a6-ad17-476754408cf8'	System	27 Aug 2020 17:00:30
User entered '27 Aug 2020 12:00'	System	27 Aug 2020 17:00:30



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Aug 2020 00:07:15
User entered 'Day 18'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-28T12:27:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd48d4e0f-a0e8-4ef5-b3d3-eb38d7c9fd1c'	System	28 Aug 2020 17:27:38
User entered 'No interference with activity (1)'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-28T12:27:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd48d4e0f-a0e8-4ef5-b3d3-eb38d7c9fd1c' User entered '28 Aug 2020 12:27'	System	28 Aug 2020 17:27:38
	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Aug 2020 17:00:30
User entered 'Day 19'	System	27 Aug 2020 17:00:30



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-29T12:44:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd199b356-3df9-43de-a346-b22b1d7ef6d8'	System	29 Aug 2020 17:45:00
User entered 'No interference with activity (1)'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-29T12:44:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd199b356-3df9-43de-a346-b22b1d7ef6d8' User entered '29 Aug 2020 12:44'	System	29 Aug 2020 17:45:00
	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Aug 2020 17:27:38
User entered 'Day 20'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-30T13:00:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd3b6d1ef-5d77-4ac8-aa4c-ec854b51886c'	System	30 Aug 2020 18:00:30
User entered 'No interference with activity (1)'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-30T13:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd3b6d1ef-5d77-4ac8-aa4c-ec854b51886c' User entered '30 Aug 2020 13:00'	System	30 Aug 2020 18:00:30
	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:27:38



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Aug 2020 17:45:00
User entered 'Day 21'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-31T12:02:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c4126d30-3662-4651-9699-d144205a721c'	System	31 Aug 2020 17:14:40
User entered 'No interference with activity (1)'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-31T12:02:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c4126d30-3662-4651-9699-d144205a721c' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:40
	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Aug 2020 18:00:30
User entered 'Day 22'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-01T14:28:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8f0e9d03-0b69-4555-8714-340ece5804a5'	System	01 Sep 2020 19:28:56
User entered 'No interference with activity (1)'	System	01 Sep 2020 19:28:56



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-01T14:28:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8f0e9d03-0b69-4555-8714-340ece5804a5' User entered '01 Sep 2020 14:28'	System	01 Sep 2020 19:28:56
	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Aug 2020 17:14:40
User entered 'Day 23'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-02T17:23:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '23a3ed52-c193-4907-b88c-0c3a7f87af0a'	System	02 Sep 2020 22:23:53
User entered 'No interference with activity (1)'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-02T17:23:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '23a3ed52-c193-4907-b88c-0c3a7f87af0a'	System	02 Sep 2020 22:23:53
User entered '02 Sep 2020 17:23'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:14:40



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Sep 2020 19:28:56
User entered 'Day 24'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-03T12:00:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '39374a81-43f1-4add-bbe0-e27168609352'	System	03 Sep 2020 17:00:37
User entered 'No interference with activity (1)'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-03T12:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '39374a81-43f1-4add-bbe0-e27168609352' User entered '03 Sep 2020 12:00'	System	03 Sep 2020 17:00:37
	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Sep 2020 22:23:53
User entered 'Day 25'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-04T12:00:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f0b551ac-3c58-4107-9632-1ecc2573956f' User entered 'No interference with activity (1)'	System	04 Sep 2020 17:00:38
	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-04T12:00:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f0b551ac-3c58-4107-9632-1ecc2573956f' User entered '04 Sep 2020 12:00'	System	04 Sep 2020 17:00:38
	System	04 Sep 2020 17:00:38



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Sep 2020 17:00:37
User entered 'Day 26'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-05T12:05:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fc168bef-422a-4945-a0fd-07dd40647c65'	System	05 Sep 2020 17:05:14
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-05T12:05:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fc168bef-422a-4945-a0fd-07dd40647c65'	System	05 Sep 2020 17:05:14
User entered '05 Sep 2020 12:05'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Sep 2020 17:00:38
User entered 'Day 27'	System	04 Sep 2020 17:00:38



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-06T12:25:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1ae2cfd-bf44-4c20-95de-1e788facad2a' User entered 'No interference with activity (1)'	System	06 Sep 2020 17:25:05
	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-06T12:25:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1ae2cfd-bf44-4c20-95de-1e788facad2a' User entered '06 Sep 2020 12:25'	System	06 Sep 2020 17:25:05
	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Sep 2020 17:05:14
User entered 'Day 28'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-07T12:00:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '129c95e3-55e0-421f-a248-6c70de07b8be' User entered 'No interference with activity (1)'	System	07 Sep 2020 17:00:55
	System	07 Sep 2020 17:00:55

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-07T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '129c95e3-55e0-421f-a248-6c70de07b8be' User entered '07 Sep 2020 12:00'	System	07 Sep 2020 17:00:55
	System	07 Sep 2020 17:00:55

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:05:14



US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Sep 2020 17:25:05
User entered 'Day 29'	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:00:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '250e8ba4-87f0-429f-9d7d-c7d67046394a'	System	08 Sep 2020 17:00:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:00:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '250e8ba4-87f0-429f-9d7d-c7d67046394a' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:00:56
	System	08 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Aug 2020 17:10:19
User entered 'Day 8'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ae9cd14-97ef-4a29-9898-e24fbf5b9b5e'	System	18 Aug 2020 17:06:33
User entered 'No (N)'	System	18 Aug 2020 17:06:33



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-18T12:06:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ae9cd14-97ef-4a29-9898-e24fbf5b9b5e'	System	18 Aug 2020 17:06:33
User entered '18 Aug 2020 12:06'	System	18 Aug 2020 17:06:33

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:10:19

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Aug 2020 17:36:26
User entered 'Day 9'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '897c889b-fb90-4b3c-989b-380c5d118f70'	System	19 Aug 2020 17:13:45
User entered 'No (N)'	System	19 Aug 2020 17:13:45

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-19T12:13:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '897c889b-fb90-4b3c-989b-380c5d118f70'	System	19 Aug 2020 17:13:45
User entered '19 Aug 2020 12:13'	System	19 Aug 2020 17:13:45

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:36:26

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:36:26



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Aug 2020 17:05:56
User entered 'Day 10'	System	18 Aug 2020 17:05:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9b7c5b06-ced8-4ef8-bb65-7a7d3a1c30bd' User entered 'No (N)'	System	21 Aug 2020 11:01:55
	System	21 Aug 2020 11:01:55

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-21T06:01:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9b7c5b06-ced8-4ef8-bb65-7a7d3a1c30bd' User entered '21 Aug 2020 06:01'	System	21 Aug 2020 11:01:55
	System	21 Aug 2020 11:01:55

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:05:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:05:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
DataPoint Activated.	System	21 Aug 2020 11:01:44
DataPoint Inactivated.	System	21 Aug 2020 11:01:31
Data entry locked.	System	19 Aug 2020 17:13:23
User entered 'Day 11'	System	19 Aug 2020 17:13:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T06:00:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b538b0ae-4c0c-4c83-90ca-d7d13f8eecbb'	System	22 Aug 2020 11:00:57
User entered 'No (N)'	System	22 Aug 2020 11:00:57
DataPoint Activated.	System	21 Aug 2020 11:01:44
DataPoint Inactivated.	System	21 Aug 2020 11:01:31

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-22T06:00:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b538b0ae-4c0c-4c83-90ca-d7d13f8eecbb'	System	22 Aug 2020 11:00:57
User entered '22 Aug 2020 06:00'	System	22 Aug 2020 11:00:57
DataPoint Activated.	System	21 Aug 2020 11:01:44
DataPoint Inactivated.	System	21 Aug 2020 11:01:31



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
DataPoint Activated.	System	21 Aug 2020 11:01:44
DataPoint Inactivated.	System	21 Aug 2020 11:01:31
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:13:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
DataPoint Activated.	System	21 Aug 2020 11:01:44
DataPoint Inactivated.	System	21 Aug 2020 11:01:31
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:13:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Aug 2020 11:01:44
User entered 'Day 12'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T00:00:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd09a83af-c2d8-4a18-9221-7b46e7e4e17f' User entered 'No (N)'	System	23 Aug 2020 05:00:14
	System	23 Aug 2020 05:00:14

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T00:00:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd09a83af-c2d8-4a18-9221-7b46e7e4e17f' User entered '23 Aug 2020 00:00'	System	23 Aug 2020 05:00:14
	System	23 Aug 2020 05:00:14

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 11:01:44

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Aug 2020 11:00:46
User entered 'Day 13'	System	22 Aug 2020 11:00:46



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T13:19:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2af9eb49-8ae9-43f9-aef2-5a8ec0b94981'	System	23 Aug 2020 18:19:36
User entered 'No (N)'	System	23 Aug 2020 18:19:36

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-23T13:19:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2af9eb49-8ae9-43f9-aef2-5a8ec0b94981' User entered '23 Aug 2020 13:19'	System	23 Aug 2020 18:19:36
	System	23 Aug 2020 18:19:36

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 11:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Aug 2020 05:00:04
User entered 'Day 14'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-24T12:12:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78e63d90-6654-467f-a992-09f9c5be202a' User entered 'No (N)'	System	24 Aug 2020 17:12:39
	System	24 Aug 2020 17:12:39

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-24T12:12:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '78e63d90-6654-467f-a992-09f9c5be202a' User entered '24 Aug 2020 12:12'	System	24 Aug 2020 17:12:39
	System	24 Aug 2020 17:12:39

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 05:00:04



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 05:00:04

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Aug 2020 18:19:30
User entered 'Day 15'	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-25T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f98ecd1a-7e80-45aa-8f0d-d4ec4a0aed73'	System	25 Aug 2020 17:00:50
User entered 'No (N)'	System	25 Aug 2020 17:00:50

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-25T12:00:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f98ecd1a-7e80-45aa-8f0d-d4ec4a0aed73'	System	25 Aug 2020 17:00:50
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:50

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 18:19:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Aug 2020 17:12:23
User entered 'Day 16'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-26T19:07:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '475b419e-ae5a-42e6-afda-ba20209f4b58'	System	27 Aug 2020 00:07:26
User entered 'No (N)'	System	27 Aug 2020 00:07:26



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-26T19:07:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '475b419e-ae5a-42e6-afda-ba20209f4b58'	System	27 Aug 2020 00:07:26
User entered '26 Aug 2020 19:07'	System	27 Aug 2020 00:07:26

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:12:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Aug 2020 17:00:30
User entered 'Day 17'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-27T12:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '826ac4f0-2f66-4361-b50c-faf0f49c4b87'	System	27 Aug 2020 17:00:47
User entered 'No (N)'	System	27 Aug 2020 17:00:47

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-27T12:00:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '826ac4f0-2f66-4361-b50c-faf0f49c4b87'	System	27 Aug 2020 17:00:47
User entered '27 Aug 2020 12:00'	System	27 Aug 2020 17:00:47

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 17:00:30



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Aug 2020 00:07:15
User entered 'Day 18'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-28T12:27:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '816a350c-c4be-4077-a119-faff72b66bdc' User entered 'No (N)'	System	28 Aug 2020 17:27:45
	System	28 Aug 2020 17:27:45

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-28T12:27:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '816a350c-c4be-4077-a119-faff72b66bdc' User entered '28 Aug 2020 12:27'	System	28 Aug 2020 17:27:45
	System	28 Aug 2020 17:27:45

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 00:07:15

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Aug 2020 17:00:30
User entered 'Day 19'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-29T12:44:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '871a315d-61b8-482f-92ec-f8022189f3aa'	System	29 Aug 2020 17:45:08
User entered 'No (N)'	System	29 Aug 2020 17:45:08

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-29T12:45:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '871a315d-61b8-482f-92ec-f8022189f3aa'	System	29 Aug 2020 17:45:08
User entered '29 Aug 2020 12:45'	System	29 Aug 2020 17:45:08



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Aug 2020 17:27:38
User entered 'Day 20'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-30T13:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bae396ae-667b-45c4-a8a5-137176cfbc35'	System	30 Aug 2020 18:00:37
User entered 'No (N)'	System	30 Aug 2020 18:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-30T13:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bae396ae-667b-45c4-a8a5-137176cfbc35'	System	30 Aug 2020 18:00:37
User entered '30 Aug 2020 13:00'	System	30 Aug 2020 18:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:27:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Aug 2020 17:45:00
User entered 'Day 21'	System	29 Aug 2020 17:45:00



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-31T12:02:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2d08014b-c96d-432a-82b5-0a4ea5d787e3'	System	31 Aug 2020 17:14:48
User entered 'No (N)'	System	31 Aug 2020 17:14:48

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-08-31T12:02:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2d08014b-c96d-432a-82b5-0a4ea5d787e3' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:48
	System	31 Aug 2020 17:14:48

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:45:00

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Aug 2020 18:00:30
User entered 'Day 22'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-01T14:29:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '71fec6ad-3c08-48b1-a104-1daf9c0f5c9a' User entered 'No (N)'	System	01 Sep 2020 19:29:38
	System	01 Sep 2020 19:29:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-01T14:29:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '71fec6ad-3c08-48b1-a104-1daf9c0f5c9a'	System	01 Sep 2020 19:29:38
User entered '01 Sep 2020 14:29'	System	01 Sep 2020 19:29:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:00:30



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:00:30

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Aug 2020 17:14:40
User entered 'Day 23'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-02T17:23:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b2630313-0ca3-4e11-9f28-54bc192a4093' User entered 'No (N)'	System	02 Sep 2020 22:24:04
	System	02 Sep 2020 22:24:04

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-02T17:24:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b2630313-0ca3-4e11-9f28-54bc192a4093'	System	02 Sep 2020 22:24:04
User entered '02 Sep 2020 17:24'	System	02 Sep 2020 22:24:04

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:14:40

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Sep 2020 19:28:56
User entered 'Day 24'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-03T12:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468de1c5-8ff2-4b4b-8413-d5cba61329c8'	System	03 Sep 2020 17:00:45
User entered 'No (N)'	System	03 Sep 2020 17:00:45



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-03T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '468de1c5-8ff2-4b4b-8413-d5cba61329c8'	System	03 Sep 2020 17:00:45
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 17:00:45

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:28:56

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Sep 2020 22:23:53
User entered 'Day 25'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-04T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '15724b61-5dcb-4bcb-ac6a-3d238ea335be' User entered 'No (N)'	System	04 Sep 2020 17:00:46
	System	04 Sep 2020 17:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-04T12:00:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '15724b61-5dc6-4bcb-ac6a-3d238ea335be' User entered '04 Sep 2020 12:00'	System	04 Sep 2020 17:00:46
	System	04 Sep 2020 17:00:46

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:23:53

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:23:53



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Sep 2020 17:00:37
User entered 'Day 26'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-05T12:05:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '492c1512-faf6-4ad2-b02f-0a18d66512aa' User entered 'No (N)'	System	05 Sep 2020 17:05:25
	System	05 Sep 2020 17:05:25

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-05T12:05:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '492c1512-faf6-4ad2-b02f-0a18d66512aa' User entered '05 Sep 2020 12:05'	System	05 Sep 2020 17:05:25
	System	05 Sep 2020 17:05:25

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:00:37

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Sep 2020 17:00:38
User entered 'Day 27'	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-06T12:25:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1a77f42-b21f-40de-8d4d-c1197de5b46a' User entered 'No (N)'	System	06 Sep 2020 17:25:17
	System	06 Sep 2020 17:25:17

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-06T12:25:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1a77f42-b21f-40de-8d4d-c1197de5b46a' User entered '06 Sep 2020 12:25'	System	06 Sep 2020 17:25:17
	System	06 Sep 2020 17:25:17



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Sep 2020 17:05:14
User entered 'Day 28'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-07T12:01:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1ee38e0f-17d4-4c05-9be2-34cf1bdf58ee' User entered 'No (N)'	System	07 Sep 2020 17:01:23
	System	07 Sep 2020 17:01:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-07T12:01:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1ee38e0f-17d4-4c05-9be2-34cf1bdf58ee' User entered '07 Sep 2020 12:01'	System	07 Sep 2020 17:01:23
	System	07 Sep 2020 17:01:23

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:05:14

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Sep 2020 17:25:05
User entered 'Day 29'	System	06 Sep 2020 17:25:05



US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1480cd8d-5753-4064-8e26-0f09d0104c76' User entered 'No (N)'	System	08 Sep 2020 17:01:20
	System	08 Sep 2020 17:01:20

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:00:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1480cd8d-5753-4064-8e26-0f09d0104c76' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:01:20
	System	08 Sep 2020 17:01:20

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:25:05

US3292128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:25:05

US3292128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:07:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Sep 2020 20:48:40
DataPoint Verified.	(b) (4)	29 Sep 2020 20:48:28
User entered 'Yes (Y)'	Dawn Killian (b) (4)	19 Aug 2020 02:21:21
	(b) (4)	

US3292128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:07:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Sep 2020 20:48:41
DataPoint Verified.	(b) (4)	29 Sep 2020 20:48:28
User entered '18 Aug 2020'	(b) (4)	19 Aug 2020 02:21:21

US3292128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4)	05 Mar 2021 15:07:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Un-verified.	(b) (4)	(b) (4), (b) (6) 29 Sep 2020 20:48:43
DataPoint Verified.	(b) (4)	29 Sep 2020 20:48:28
User entered 'Contact Made (CONTACT MADE)'	Dawn Killian (b) (4)	19 Aug 2020 02:21:21
	(b) (4)	

US3292128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4)	05 Mar 2021 15:07:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Sep 2020 20:48:45
DataPoint Verified.	(b) (4)	29 Sep 2020 20:48:28
User entered empty.	Dawn Killian (b) (4)	19 Aug 2020 02:21:21
	(b) (4)	



US3292128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		08 Apr 2021 18:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:21:28

US3292128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	19 Aug 2020 02:21:28

US3292128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:08
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	26 Aug 2020 22:07:40

US3292128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:08
User entered '26 Aug 2020'	Kristy Trevino (b) (4)	26 Aug 2020 22:07:40

US3292128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:49:08
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 22:07:40

US3292128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:08
User entered empty.	Kristy Trevino (b) (4)	26 Aug 2020 22:07:40

US3292128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:48:56
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	26 Aug 2020 22:07:46

**US3292128**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	26 Aug 2020 22:07:46



US3292128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:28
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Sep 2020 05:22:20

US3292128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:28
User entered '1 Sep 2020'	Kristy Trevino (b) (4)	02 Sep 2020 05:22:20

US3292128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:49:28
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:22:20

US3292128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:28
User entered empty.	Kristy Trevino (b) (4)	02 Sep 2020 05:22:20

US3292128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:30
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Sep 2020 05:22:25

US3292128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	02 Sep 2020 05:22:25

US3292128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:05:00
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:10:28

US3292128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:05:00
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:10:28



US3292128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:05:00
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	08 Sep 2020 18:10:28

US3292128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'VISIT2'	System	08 Sep 2020 18:10:28

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '11:27'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '8 Sep 2020 11:27'	System	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '36.2' C	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13



US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered empty.	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '69'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'bpm'	System	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '15'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'breaths/min'	System	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '142'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	08 Sep 2020 18:15:13



US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '81'	Gerardo Pena (b) (4)	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	08 Sep 2020 18:15:13

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '12:44'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '8 Sep 2020 12:44'	System	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '36.8' C	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49



US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered empty.	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '70'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'bpm'	System	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '16'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'breaths/min'	System	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '131'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	08 Sep 2020 18:27:49



US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:22
User entered '74'	Gerardo Pena (b) (4)	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	08 Sep 2020 18:27:49

US3292128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:37
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:09

US3292128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:07:37
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:09

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:08:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:08:22
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

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)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:08:22
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:35:34



US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:08:22
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:08:22
User entered '12:14'	(b) (4), (b) (6)	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '8 Sep 2020 12:14'	System	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:08:22
User entered 'Left Arm (LEFT ARM)'		08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		13 Jan 2021 20:08:22
User entered 'ONCE'		08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:35:34

US3292128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:08:52
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:38

US3292128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:08:52
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:38



US3292128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:08:52
User entered '11:40'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:38

US3292128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '8 Sep 2020 11:40'	System	08 Sep 2020 18:28:38

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:23
User entered '8 Sep 2020'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:55

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 18:28:55

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:23
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:55

**US3292128**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:23
User entered '11:50'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:55

**US3292128**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '8 Sep 2020 11:50'	System	08 Sep 2020 18:28:55

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 18:28:55



US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:23
User entered 'No (N)'	Gerardo Pena (b) (4)	08 Sep 2020 18:28:55

US3292128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:23
User entered empty.	Gerardo Pena (b) (4)	08 Sep 2020 18:28:55

**US3292128**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered empty.	System	08 Sep 2020 18:28:55

US3292128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:09:53
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	08 Sep 2020 18:29:04

US3292128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'I'	System	08 Sep 2020 18:29:04

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7d9a3b0-96f6-42a0-965f-f14b1852763b' User entered 'Yes (Y)'	System	08 Sep 2020 17:46:45
	System	08 Sep 2020 17:46:45

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7d9a3b0-96f6-42a0-965f-f14b1852763b' User entered '98.2'	System	08 Sep 2020 17:46:45
	System	08 Sep 2020 17:46:45



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7d9a3b0-96f6-42a0-965f-f14b1852763b' User entered 'No (N)'	System	08 Sep 2020 17:46:45
	System	08 Sep 2020 17:46:45

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7d9a3b0-96f6-42a0-965f-f14b1852763b' User entered '08 Sep 2020 12:46'	System	08 Sep 2020 17:46:45
	System	08 Sep 2020 17:46:45

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 12:34'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:04'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:14:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '574b2896-c77f-4166-97a0-101ae98f61f5' User entered 'Yes (Y)'	System	08 Sep 2020 22:15:14
	System	08 Sep 2020 22:15:14

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '574b2896-c77f-4166-97a0-101ae98f61f5' User entered '98.5'	System	08 Sep 2020 22:15:14
	System	08 Sep 2020 22:15:14

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '574b2896-c77f-4166-97a0-101ae98f61f5'	System	08 Sep 2020 22:15:14
User entered 'No (N)'	System	08 Sep 2020 22:15:14



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '574b2896-c77f-4166-97a0-101ae98f61f5'	System	08 Sep 2020 22:15:14
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 22:15:14

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 2'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:55:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd4d7d616-e761-430e-a40a-2f283f568d7e' User entered 'Yes (Y)'	System	09 Sep 2020 19:56:09
	System	09 Sep 2020 19:56:09

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:55:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd4d7d616-e761-430e-a40a-2f283f568d7e' User entered '98.2'	System	09 Sep 2020 19:56:09
	System	09 Sep 2020 19:56:09

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:55:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd4d7d616-e761-430e-a40a-2f283f568d7e'	System	09 Sep 2020 19:56:09
User entered 'No (N)'	System	09 Sep 2020 19:56:09

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd4d7d616-e761-430e-a40a-2f283f568d7e' User entered '09 Sep 2020 14:56'	System	09 Sep 2020 19:56:09
	System	09 Sep 2020 19:56:09



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 3'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '206b3e8c-ef94-4f2a-b434-427762fe8c60'	System	10 Sep 2020 19:27:23
User entered 'Yes (Y)'	System	10 Sep 2020 19:27:23

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '206b3e8c-ef94-4f2a-b434-427762fe8c60' User entered '98.0'	System	10 Sep 2020 19:27:23
	System	10 Sep 2020 19:27:23

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '206b3e8c-ef94-4f2a-b434-427762fe8c60'	System	10 Sep 2020 19:27:23
User entered 'No (N)'	System	10 Sep 2020 19:27:23

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '206b3e8c-ef94-4f2a-b434-427762fe8c60'	System	10 Sep 2020 19:27:23
User entered '10 Sep 2020 14:27'	System	10 Sep 2020 19:27:23

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 4'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:46:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd49ace7a-c7d6-461f-a27f-7ed5ace94018' User entered 'Yes (Y)'	System	11 Sep 2020 20:46:35
	System	11 Sep 2020 20:46:35

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:46:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd49ace7a-c7d6-461f-a27f-7ed5ace94018' User entered '98.6'	System	11 Sep 2020 20:46:35
	System	11 Sep 2020 20:46:35

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:46:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd49ace7a-c7d6-461f-a27f-7ed5ace94018'	System	11 Sep 2020 20:46:35
User entered 'No (N)'	System	11 Sep 2020 20:46:35

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:46:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd49ace7a-c7d6-461f-a27f-7ed5ace94018'	System	11 Sep 2020 20:46:35
User entered '11 Sep 2020 15:46'	System	11 Sep 2020 20:46:35

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 5'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4aa47a9e-2bf1-476b-8ebe-1009f6532fe8' User entered 'Yes (Y)'	System	12 Sep 2020 17:05:22
	System	12 Sep 2020 17:05:22

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4aa47a9e-2bf1-476b-8ebe-1009f6532fe8' User entered '98.2'	System	12 Sep 2020 17:05:22
	System	12 Sep 2020 17:05:22

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4aa47a9e-2bf1-476b-8ebe-1009f6532fe8'	System	12 Sep 2020 17:05:22
User entered 'No (N)'	System	12 Sep 2020 17:05:22

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4aa47a9e-2bf1-476b-8ebe-1009f6532fe8'	System	12 Sep 2020 17:05:22
User entered '12 Sep 2020 12:05'	System	12 Sep 2020 17:05:22

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 6'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e1d63efa-2c06-48a3-bf8a-90261ee04639'	System	13 Sep 2020 19:21:34
User entered 'Yes (Y)'	System	13 Sep 2020 19:21:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e1d63efa-2c06-48a3-bf8a-90261ee04639' User entered '98.2'	System	13 Sep 2020 19:21:34
	System	13 Sep 2020 19:21:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e1d63efa-2c06-48a3-bf8a-90261ee04639'	System	13 Sep 2020 19:21:34
User entered 'No (N)'	System	13 Sep 2020 19:21:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e1d63efa-2c06-48a3-bf8a-90261ee04639'	System	13 Sep 2020 19:21:34
User entered '13 Sep 2020 14:21'	System	13 Sep 2020 19:21:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 7'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:10:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8622db71-28f9-4512-933e-f1888cc420a0'	System	14 Sep 2020 17:10:32
User entered 'Yes (Y)'	System	14 Sep 2020 17:10:32



US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:10:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8622db71-28f9-4512-933e-f1888cc420a0' User entered '97.8'	System	14 Sep 2020 17:10:32
	System	14 Sep 2020 17:10:32

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:10:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8622db71-28f9-4512-933e-f1888cc420a0'	System	14 Sep 2020 17:10:32
User entered 'No (N)'	System	14 Sep 2020 17:10:32

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:10:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8622db71-28f9-4512-933e-f1888cc420a0' User entered '14 Sep 2020 12:10'	System	14 Sep 2020 17:10:32
	System	14 Sep 2020 17:10:32

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '375c185e-5443-4da1-8aa0-2b272bfa63cf' User entered 'None (1)'	System	08 Sep 2020 17:47:13
	System	08 Sep 2020 17:47:13

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:46:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '375c185e-5443-4da1-8aa0-2b272bfa63cf' User entered 'No (N)'	System	08 Sep 2020 17:47:13
	System	08 Sep 2020 17:47:13



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '375c185e-5443-4da1-8aa0-2b272bfa63cf' User entered 'No (N)'	System	08 Sep 2020 17:47:13
	System	08 Sep 2020 17:47:13

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '375c185e-5443-4da1-8aa0-2b272bfa63cf' User entered 'None (1)'	System	08 Sep 2020 17:47:13
	System	08 Sep 2020 17:47:13

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '375c185e-5443-4da1-8aa0-2b272bfa63cf' User entered '08 Sep 2020 12:47'	System	08 Sep 2020 17:47:13
	System	08 Sep 2020 17:47:13

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 12:34'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:04'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3059f27e-3d5f-4de4-8afc-45d16543c2ab'	System	08 Sep 2020 22:15:58
User entered 'None (1)'	System	08 Sep 2020 22:15:58

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3059f27e-3d5f-4de4-8afc-45d16543c2ab' User entered 'No (N)'	System	08 Sep 2020 22:15:58
	System	08 Sep 2020 22:15:58



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3059f27e-3d5f-4de4-8afc-45d16543c2ab' User entered 'No (N)'	System	08 Sep 2020 22:15:58
	System	08 Sep 2020 22:15:58

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3059f27e-3d5f-4de4-8afc-45d16543c2ab'	System	08 Sep 2020 22:15:58
User entered 'None (1)'	System	08 Sep 2020 22:15:58

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:15:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3059f27e-3d5f-4de4-8afc-45d16543c2ab'	System	08 Sep 2020 22:15:58
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 22:15:58

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 2'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62167ba9-5e86-4de9-9bf3-52d30f972396'	System	09 Sep 2020 19:56:31
User entered 'None (1)'	System	09 Sep 2020 19:56:31

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62167ba9-5e86-4de9-9bf3-52d30f972396'	System	09 Sep 2020 19:56:31
User entered 'No (N)'	System	09 Sep 2020 19:56:31



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62167ba9-5e86-4de9-9bf3-52d30f972396'	System	09 Sep 2020 19:56:31
User entered 'No (N)'	System	09 Sep 2020 19:56:31

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62167ba9-5e86-4de9-9bf3-52d30f972396'	System	09 Sep 2020 19:56:31
User entered 'None (1)'	System	09 Sep 2020 19:56:31

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62167ba9-5e86-4de9-9bf3-52d30f972396' User entered '09 Sep 2020 14:56'	System	09 Sep 2020 19:56:31
	System	09 Sep 2020 19:56:31

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 3'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6814f7b7-a2c7-4475-92e5-1c64bd0b1c31' User entered 'None (1)'	System	10 Sep 2020 19:27:47
	System	10 Sep 2020 19:27:47

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6814f7b7-a2c7-4475-92e5-1c64bd0b1c31' User entered 'No (N)'	System	10 Sep 2020 19:27:47
	System	10 Sep 2020 19:27:47



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6814f7b7-a2c7-4475-92e5-1c64bd0b1c31' User entered 'No (N)'	System	10 Sep 2020 19:27:47
	System	10 Sep 2020 19:27:47

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6814f7b7-a2c7-4475-92e5-1c64bd0b1c31' User entered 'None (1)'	System	10 Sep 2020 19:27:47
	System	10 Sep 2020 19:27:47

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6814f7b7-a2c7-4475-92e5-1c64bd0b1c31' User entered '10 Sep 2020 14:27'	System	10 Sep 2020 19:27:47
	System	10 Sep 2020 19:27:47

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 4'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:46:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '86259fc1-2334-4a3b-8b9a-9c9bf63bc99a' User entered 'None (1)'	System	11 Sep 2020 20:47:26
	System	11 Sep 2020 20:47:26

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '86259fc1-2334-4a3b-8b9a-9c9bf63bc99a'	System	11 Sep 2020 20:47:26
User entered 'No (N)'	System	11 Sep 2020 20:47:26



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '86259fc1-2334-4a3b-8b9a-9c9bf63bc99a'	System	11 Sep 2020 20:47:26
User entered 'No (N)'	System	11 Sep 2020 20:47:26

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '86259fc1-2334-4a3b-8b9a-9c9bf63bc99a' User entered 'None (1)'	System	11 Sep 2020 20:47:26
	System	11 Sep 2020 20:47:26

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '86259fc1-2334-4a3b-8b9a-9c9bf63bc99a'	System	11 Sep 2020 20:47:26
User entered '11 Sep 2020 15:47'	System	11 Sep 2020 20:47:26

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 5'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '255f3b7a-2806-4e8d-ac10-e135324a0e23'	System	12 Sep 2020 17:05:48
User entered 'None (1)'	System	12 Sep 2020 17:05:48

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '255f3b7a-2806-4e8d-ac10-e135324a0e23'	System	12 Sep 2020 17:05:48
User entered 'No (N)'	System	12 Sep 2020 17:05:48



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '255f3b7a-2806-4e8d-ac10-e135324a0e23'	System	12 Sep 2020 17:05:48
User entered 'No (N)'	System	12 Sep 2020 17:05:48

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '255f3b7a-2806-4e8d-ac10-e135324a0e23'	System	12 Sep 2020 17:05:48
User entered 'None (1)'	System	12 Sep 2020 17:05:48

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '255f3b7a-2806-4e8d-ac10-e135324a0e23'	System	12 Sep 2020 17:05:48
User entered '12 Sep 2020 12:05'	System	12 Sep 2020 17:05:48

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 6'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '26b08a46-adf8-41ab-b8eb-789a65ac5e28'	System	13 Sep 2020 19:22:28
User entered 'None (1)'	System	13 Sep 2020 19:22:28

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:21:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '26b08a46-adf8-41ab-b8eb-789a65ac5e28'	System	13 Sep 2020 19:22:28
User entered 'No (N)'	System	13 Sep 2020 19:22:28



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '26b08a46-adf8-41ab-b8eb-789a65ac5e28' User entered 'No (N)'	System	13 Sep 2020 19:22:28
	System	13 Sep 2020 19:22:28

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '26b08a46-adf8-41ab-b8eb-789a65ac5e28'	System	13 Sep 2020 19:22:28
User entered 'None (1)'	System	13 Sep 2020 19:22:28

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '26b08a46-adf8-41ab-b8eb-789a65ac5e28'	System	13 Sep 2020 19:22:28
User entered '13 Sep 2020 14:22'	System	13 Sep 2020 19:22:28

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 7'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb89c39d-044f-41c9-b6d6-e993cfc46c5c'	System	14 Sep 2020 17:11:54
User entered 'None (1)'	System	14 Sep 2020 17:11:54

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb89c39d-044f-41c9-b6d6-e993cfc46c5c'	System	14 Sep 2020 17:11:54
User entered 'No (N)'	System	14 Sep 2020 17:11:54



US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb89c39d-044f-41c9-b6d6-e993cfc46c5c'	System	14 Sep 2020 17:11:54
User entered 'No (N)'	System	14 Sep 2020 17:11:54

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb89c39d-044f-41c9-b6d6-e993cfc46c5c'	System	14 Sep 2020 17:11:54
User entered 'None (1)'	System	14 Sep 2020 17:11:54

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb89c39d-044f-41c9-b6d6-e993cfc46c5c'	System	14 Sep 2020 17:11:54
User entered '14 Sep 2020 12:11'	System	14 Sep 2020 17:11:54

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered 'None (0)'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered 'None (0)'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4'	System	08 Sep 2020 17:47:46
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4'	System	08 Sep 2020 17:47:46
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered 'None (0)'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered 'None (0)'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered 'No (N)'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T12:47:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6fa864aa-c69b-4fd9-a421-9d44c9fe31c4' User entered '08 Sep 2020 12:47'	System	08 Sep 2020 17:47:46
	System	08 Sep 2020 17:47:46

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 12:34'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:04'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'None (0)'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69' User entered 'None (0)'	System	08 Sep 2020 22:16:52
	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'None (0)'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered 'No (N)'	System	08 Sep 2020 22:16:52



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-08T17:16:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '590fc443-fda0-4147-97c1-e4e7d46bcb69'	System	08 Sep 2020 22:16:52
User entered '08 Sep 2020 17:16'	System	08 Sep 2020 22:16:52

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Sep 2020 15:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 2'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered 'None (0)'	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:56:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered 'No interference with activity (1)'	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered 'No interference with activity (1)'	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered 'No interference with activity (1)'	System	09 Sep 2020 19:57:30



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63' User entered 'None (0)'	System	09 Sep 2020 19:57:30
	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63' User entered 'None (0)'	System	09 Sep 2020 19:57:30
	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered 'No (N)'	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-09T14:57:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9897e9c0-7a42-4a4e-a8ee-63af5f1fac63'	System	09 Sep 2020 19:57:30
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 19:57:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 3'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9' User entered 'None (0)'	System	10 Sep 2020 19:28:24
	System	10 Sep 2020 19:28:24



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:27:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9' User entered 'None (0)'	System	10 Sep 2020 19:28:24
	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9'	System	10 Sep 2020 19:28:24
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9'	System	10 Sep 2020 19:28:24
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9' User entered 'None (0)'	System	10 Sep 2020 19:28:24
	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9' User entered 'None (0)'	System	10 Sep 2020 19:28:24
	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9'	System	10 Sep 2020 19:28:24
User entered 'No (N)'	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-10T14:28:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '623c15e2-96dc-467f-8930-5f1dcc3893f9' User entered '10 Sep 2020 14:28'	System	10 Sep 2020 19:28:24
	System	10 Sep 2020 19:28:24

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 4'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136' User entered 'None (0)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136'	System	11 Sep 2020 20:48:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136'	System	11 Sep 2020 20:48:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:45', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136'	System	11 Sep 2020 20:48:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136' User entered 'None (0)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136' User entered 'None (0)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:47:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136' User entered 'No (N)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-11T15:48:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5aefca6a-6d4d-413a-b46a-fd8226167136'	System	11 Sep 2020 20:48:03
User entered '11 Sep 2020 15:48'	System	11 Sep 2020 20:48:03

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 5'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:05:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898' User entered 'None (0)'	System	12 Sep 2020 17:06:30
	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:06:30



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898' User entered 'None (0)'	System	12 Sep 2020 17:06:30
	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered 'None (0)'	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered 'No (N)'	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-12T12:06:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '11fac1c6-11c4-48eb-8fcb-b8af75d6d898'	System	12 Sep 2020 17:06:30
User entered '12 Sep 2020 12:06'	System	12 Sep 2020 17:06:30

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 6'	System	08 Sep 2020 17:35:34



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'None (0)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe'	System	13 Sep 2020 19:23:06
User entered 'No interference with activity (1)'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'No interference with activity (1)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'No interference with activity (1)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'None (0)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'None (0)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:22:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered 'No (N)'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-13T14:23:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '22b8f4d0-5047-466d-9a5a-940c1fe82abe' User entered '13 Sep 2020 14:23'	System	13 Sep 2020 19:23:06
	System	13 Sep 2020 19:23:06



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Sep 2020 17:35:34
User entered 'Day 7'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:11:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921' User entered 'None (0)'	System	14 Sep 2020 17:13:17
	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921'	System	14 Sep 2020 17:13:17
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921'	System	14 Sep 2020 17:13:17
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921'	System	14 Sep 2020 17:13:17
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921' User entered 'None (0)'	System	14 Sep 2020 17:13:17
	System	14 Sep 2020 17:13:17



US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921' User entered 'None (0)'	System	14 Sep 2020 17:13:17
	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:12:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921' User entered 'No (N)'	System	14 Sep 2020 17:13:17
	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-14T12:13:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3135101d-d3cf-448f-8ddd-5e341a03d921' User entered '14 Sep 2020 12:13'	System	14 Sep 2020 17:13:17
	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:35:34

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Sep 2020 19:23:06
User entered 'Day 8'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:16:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0b77b3bd-2993-4484-8965-8e63fcba3cce'	System	15 Sep 2020 17:17:08
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0b77b3bd-2993-4484-8965-8e63fcba3cce' User entered '15 Sep 2020 12:17'	System	15 Sep 2020 17:17:08
	System	15 Sep 2020 17:17:08



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Sep 2020 17:13:17
User entered 'Day 9'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ed91e430-4ea4-4d1a-afca-108be6e53d47'	System	16 Sep 2020 17:00:31
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ed91e430-4ea4-4d1a-afca-108be6e53d47'	System	16 Sep 2020 17:00:31
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Sep 2020 17:17:08
User entered 'Day 10'	System	15 Sep 2020 17:17:08



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '294343a4-3e1c-4f42-8ed9-168411c1a9d9'	System	17 Sep 2020 17:00:48
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '294343a4-3e1c-4f42-8ed9-168411c1a9d9'	System	17 Sep 2020 17:00:48
User entered '17 Sep 2020 12:00'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Sep 2020 17:00:31
User entered 'Day 11'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:09:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e4207783-03fd-49a0-8b55-685e4b083380'	System	19 Sep 2020 11:09:57
User entered 'No interference with activity (1)'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:09:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e4207783-03fd-49a0-8b55-685e4b083380' User entered '19 Sep 2020 06:09'	System	19 Sep 2020 11:09:57
	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:31



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Sep 2020 17:00:48
User entered 'Day 12'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a4eb4efe-ca53-41d0-8582-99f422450ab4'	System	19 Sep 2020 17:00:21
User entered 'No interference with activity (1)'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a4eb4efe-ca53-41d0-8582-99f422450ab4' User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:00:21
	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 11:09:57
User entered 'Day 13'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ebea34ce-4c4c-4144-b8b2-b376be736890'	System	20 Sep 2020 17:00:16
User entered 'No interference with activity (1)'	System	20 Sep 2020 17:00:16



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ebea34ce-4c4c-4144-b8b2-b376be736890' User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:16
	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 17:00:21
User entered 'Day 14'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53fef2f6-7f0d-454c-8580-bd4768086e35'	System	21 Sep 2020 17:02:21
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53fef2f6-7f0d-454c-8580-bd4768086e35'	System	21 Sep 2020 17:02:21
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:00:21



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Sep 2020 17:00:16
User entered 'Day 15'	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:08:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a98477ee-0a05-45b9-8712-24aab4fe85b6'	System	22 Sep 2020 17:09:28
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:08:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a98477ee-0a05-45b9-8712-24aab4fe85b6' User entered '22 Sep 2020 12:08'	System	22 Sep 2020 17:09:28
	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Sep 2020 17:02:21
User entered 'Day 16'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '67426481-3916-41f5-ac10-7a974366b8cd' User entered 'No interference with activity (1)'	System	24 Sep 2020 10:25:17
	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '67426481-3916-41f5-ac10-7a974366b8cd' User entered '24 Sep 2020 05:25'	System	24 Sep 2020 10:25:17
	System	24 Sep 2020 10:25:17



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Sep 2020 17:09:28
User entered 'Day 17'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a561e862-e129-4883-8537-06b535e85144'	System	24 Sep 2020 17:15:06
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a561e862-e129-4883-8537-06b535e85144'	System	24 Sep 2020 17:15:06
User entered '24 Sep 2020 12:15'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 10:25:17
User entered 'Day 18'	System	24 Sep 2020 10:25:17



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd1654e44-ef77-4331-a21b-0a63dde62ad4'	System	25 Sep 2020 17:01:28
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd1654e44-ef77-4331-a21b-0a63dde62ad4' User entered '25 Sep 2020 12:00'	System	25 Sep 2020 17:01:28
	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 17:15:06
User entered 'Day 19'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '14b4b417-937f-4ab8-994b-f6090711c679'	System	26 Sep 2020 17:00:44
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '14b4b417-937f-4ab8-994b-f6090711c679' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 17:00:44
	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:15:06



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Sep 2020 17:01:28
User entered 'Day 20'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f1f0cf96-7e81-4bdf-95cd-3d7cf000d540'	System	28 Sep 2020 11:02:23
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f1f0cf96-7e81-4bdf-95cd-3d7cf000d540' User entered '28 Sep 2020 06:02'	System	28 Sep 2020 11:02:23
	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Sep 2020 17:00:44
User entered 'Day 21'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c081bdab-71eb-4460-92c2-1b0750a4fd83'	System	28 Sep 2020 17:03:51
User entered 'No interference with activity (1)'	System	28 Sep 2020 17:03:51



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c081bdab-71eb-4460-92c2-1b0750a4fd83' User entered '28 Sep 2020 12:03'	System	28 Sep 2020 17:03:51
	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 11:02:23
User entered 'Day 22'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c3647f3-dfc1-4da8-b7ae-36e2f0f35ca2'	System	29 Sep 2020 17:06:20
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c3647f3-dfc1-4da8-b7ae-36e2f0f35ca2'	System	29 Sep 2020 17:06:20
User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:02:23



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 17:03:51
User entered 'Day 23'	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3caaa393-31a2-4ef2-b3be-8cb4ad088f29'	System	30 Sep 2020 17:20:19
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3caaa393-31a2-4ef2-b3be-8cb4ad088f29'	System	30 Sep 2020 17:20:19
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Sep 2020 17:06:20
User entered 'Day 24'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:39:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9e17f534-367c-4a91-9e93-8ca96c54cfa4'	System	01 Oct 2020 19:39:56
User entered 'No interference with activity (1)'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:39:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9e17f534-367c-4a91-9e93-8ca96c54cfa4'	System	01 Oct 2020 19:39:56
User entered '01 Oct 2020 14:39'	System	01 Oct 2020 19:39:56



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Sep 2020 17:20:19
User entered 'Day 25'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:02:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2674b162-ea8a-4e1c-9ec2-b4e3bd760f41'	System	02 Oct 2020 17:03:06
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:02:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2674b162-ea8a-4e1c-9ec2-b4e3bd760f41' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 17:03:06
	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Oct 2020 19:39:56
User entered 'Day 26'	System	01 Oct 2020 19:39:56



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a46a9e20-e8bd-49c8-a3d7-35c291d5b99c'	System	04 Oct 2020 10:59:20
User entered 'No interference with activity (1)'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a46a9e20-e8bd-49c8-a3d7-35c291d5b99c' User entered '04 Oct 2020 05:59'	System	04 Oct 2020 10:59:20
	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Oct 2020 17:03:06
User entered 'Day 27'	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ca2e2bc5-76e1-466d-bb9a-c30d3ce5c873'	System	04 Oct 2020 17:00:21
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ca2e2bc5-76e1-466d-bb9a-c30d3ce5c873'	System	04 Oct 2020 17:00:21
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:03:06



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 10:59:20
User entered 'Day 28'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:12:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fc61ffc2-2a4b-405f-bb49-bcb56bbbc8e0'	System	05 Oct 2020 17:12:48
User entered 'No interference with activity (1)'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:12:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fc61ffc2-2a4b-405f-bb49-bcb56bbbc8e0' User entered '05 Oct 2020 12:12'	System	05 Oct 2020 17:12:48
	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 17:00:21
User entered 'Day 29'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:43:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9bceb3c1-b320-4771-a65d-58842c63b837'	System	06 Oct 2020 17:43:54
User entered 'No interference with activity (1)'	System	06 Oct 2020 17:43:54



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:43:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9bceb3c1-b320-4771-a65d-58842c63b837' User entered '06 Oct 2020 12:43'	System	06 Oct 2020 17:43:54
	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Oct 2020 17:12:48
User entered 'Day 30'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '74e37584-1807-4e45-bf58-abfbb465b5d7'	System	07 Oct 2020 17:36:35
User entered 'No interference with activity (1)'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '74e37584-1807-4e45-bf58-abfbb465b5d7' User entered '07 Oct 2020 12:36'	System	07 Oct 2020 17:36:35
	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:12:48



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Oct 2020 17:43:54
User entered 'Day 31'	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c9b8a7ad-6753-435c-b241-32ccf650af38'	System	08 Oct 2020 18:00:32
User entered 'No interference with activity (1)'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c9b8a7ad-6753-435c-b241-32ccf650af38'	System	08 Oct 2020 18:00:32
User entered '08 Oct 2020 13:00'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Oct 2020 17:36:35
User entered 'Day 32'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6ca43301-2c19-4e1e-9ff9-2179431563e7'	System	09 Oct 2020 17:00:26
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6ca43301-2c19-4e1e-9ff9-2179431563e7' User entered '09 Oct 2020 12:00'	System	09 Oct 2020 17:00:26
	System	09 Oct 2020 17:00:26



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Oct 2020 18:00:32
User entered 'Day 33'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'dfc70f58-a970-4b8f-bf3b-a8520a62ae9d'	System	10 Oct 2020 17:24:31
User entered 'No interference with activity (1)'	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'dfc70f58-a970-4b8f-bf3b-a8520a62ae9d' User entered '10 Oct 2020 12:24'	System	10 Oct 2020 17:24:31
	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Oct 2020 17:00:26
User entered 'Day 34'	System	09 Oct 2020 17:00:26



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2de4b856-dbb3-4bd3-b6ef-c867e92763f1'	System	11 Oct 2020 17:46:32
User entered 'No interference with activity (1)'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2de4b856-dbb3-4bd3-b6ef-c867e92763f1' User entered '11 Oct 2020 12:46'	System	11 Oct 2020 17:46:32
	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Oct 2020 17:24:31
User entered 'Day 35'	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4ac3a6cb-f12e-41a0-9b36-ab0adf1fc76d'	System	12 Oct 2020 17:32:41
User entered 'No interference with activity (1)'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4ac3a6cb-f12e-41a0-9b36-ab0adf1fc76d' User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:32:41
	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:24:31



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Oct 2020 17:46:32
User entered 'Day 36'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef34bb79-cd81-4d18-b033-6df53bb66120'	System	13 Oct 2020 17:07:45
User entered 'No interference with activity (1)'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef34bb79-cd81-4d18-b033-6df53bb66120' User entered '13 Oct 2020 12:07'	System	13 Oct 2020 17:07:45
	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Oct 2020 17:32:41
User entered 'Day 37'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:00:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2e70429a-bd85-4084-b3c4-03729d997e7e'	System	14 Oct 2020 17:01:38
User entered 'No interference with activity (1)'	System	14 Oct 2020 17:01:38



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2e70429a-bd85-4084-b3c4-03729d997e7e' User entered '14 Oct 2020 12:01'	System	14 Oct 2020 17:01:38
	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Oct 2020 17:07:45
User entered 'Day 38'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:00:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd6f791b7-0b13-4763-9f37-18e9135e307b'	System	15 Oct 2020 17:01:16
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:00:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd6f791b7-0b13-4763-9f37-18e9135e307b' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 17:01:16
	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:07:45



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Oct 2020 17:01:38
User entered 'Day 39'	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '738b8e15-cef0-4638-826a-9fa5ef0f699b'	System	16 Oct 2020 17:01:24
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '738b8e15-cef0-4638-826a-9fa5ef0f699b' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 17:01:24
	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Oct 2020 17:01:16
User entered 'Day 40'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c5e951d7-e3e8-48ed-ac3a-d0af5ad17ba2'	System	18 Oct 2020 14:15:40
User entered 'No interference with activity (1)'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c5e951d7-e3e8-48ed-ac3a-d0af5ad17ba2'	System	18 Oct 2020 14:15:40
User entered '18 Oct 2020 09:15'	System	18 Oct 2020 14:15:40



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Oct 2020 17:01:24
User entered 'Day 41'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '490c772c-c424-41d5-80b1-1e9009aa69b1'	System	18 Oct 2020 17:00:24
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '490c772c-c424-41d5-80b1-1e9009aa69b1' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 17:00:24
	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 14:15:40
User entered 'Day 42'	System	18 Oct 2020 14:15:40



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9a9bd72a-2acc-4cb0-80d0-e2c82a7a495c'	System	19 Oct 2020 17:13:13
User entered 'No interference with activity (1)'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9a9bd72a-2acc-4cb0-80d0-e2c82a7a495c' User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:13
	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 17:00:24
User entered 'Day 43'	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '763403a3-e8ed-4541-8a51-5a2d58faf68a'	System	20 Oct 2020 17:00:36
User entered 'No interference with activity (1)'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '763403a3-e8ed-4541-8a51-5a2d58faf68a'	System	20 Oct 2020 17:00:36
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:24



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Oct 2020 17:13:13
User entered 'Day 44'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:49:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a1807580-f657-4dbc-a04d-223fd09c2452'	System	22 Oct 2020 01:50:09
User entered 'No interference with activity (1)'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a1807580-f657-4dbc-a04d-223fd09c2452'	System	22 Oct 2020 01:50:09
User entered '21 Oct 2020 20:50'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Oct 2020 17:00:36
User entered 'Day 45'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7fff49d1-e5e7-4810-9ce2-b9f1e7952a9e'	System	23 Oct 2020 12:19:14
User entered 'No interference with activity (1)'	System	23 Oct 2020 12:19:14



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7fff49d1-e5e7-4810-9ce2-b9f1e7952a9e'	System	23 Oct 2020 12:19:14
User entered '22 Oct 2020 12:00'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Oct 2020 01:50:09
User entered 'Day 46'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '019ea41e-16c3-45fd-9eed-b51f60b22243'	System	23 Oct 2020 17:29:16
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '019ea41e-16c3-45fd-9eed-b51f60b22243' User entered '23 Oct 2020 12:29'	System	23 Oct 2020 17:29:16
	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:50:09



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 12:19:14
User entered 'Day 47'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:10:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2b63215b-febd-4312-ab21-dd291127ebc2'	System	24 Oct 2020 17:10:55
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:10:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2b63215b-febd-4312-ab21-dd291127ebc2' User entered '24 Oct 2020 12:10'	System	24 Oct 2020 17:10:55
	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 17:29:16
User entered 'Day 48'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f3e4855e-fd4c-418f-b1cd-84d16ec34f36'	System	26 Oct 2020 10:52:47
User entered 'No interference with activity (1)'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f3e4855e-fd4c-418f-b1cd-84d16ec34f36'	System	26 Oct 2020 10:52:47
User entered '26 Oct 2020 05:52'	System	26 Oct 2020 10:52:47



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Oct 2020 17:10:55
User entered 'Day 49'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:12:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3d5e302d-8994-4cf3-96d5-0147a0d77cb3'	System	26 Oct 2020 17:12:58
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:12:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3d5e302d-8994-4cf3-96d5-0147a0d77cb3' User entered '26 Oct 2020 12:12'	System	26 Oct 2020 17:12:58
	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 10:52:47
User entered 'Day 50'	System	26 Oct 2020 10:52:47



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7064c668-aa5e-4204-892f-cf873d5bef1a'	System	27 Oct 2020 17:00:52
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7064c668-aa5e-4204-892f-cf873d5bef1a' User entered '27 Oct 2020 12:00'	System	27 Oct 2020 17:00:52
	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 17:12:58
User entered 'Day 51'	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb10ad3d-f5fa-463a-808d-af382d08ccb1'	System	28 Oct 2020 17:06:15
User entered 'No interference with activity (1)'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bb10ad3d-f5fa-463a-808d-af382d08ccb1' User entered '28 Oct 2020 12:04'	System	28 Oct 2020 17:06:15
	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:12:58



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Oct 2020 17:00:52
User entered 'Day 52'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '326166a7-a11b-43b7-bd50-51b7e15f2083'	System	29 Oct 2020 17:28:40
User entered 'No interference with activity (1)'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '326166a7-a11b-43b7-bd50-51b7e15f2083' User entered '29 Oct 2020 12:28'	System	29 Oct 2020 17:28:40
	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Oct 2020 17:06:15
User entered 'Day 53'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9cefd014-1020-40dd-9be9-6559ed0714c1'	System	30 Oct 2020 19:03:28
User entered 'No interference with activity (1)'	System	30 Oct 2020 19:03:28



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9cefd014-1020-40dd-9be9-6559ed0714c1' User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:03:28
	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Oct 2020 17:28:40
User entered 'Day 54'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '30445385-aed6-4efb-a830-312e62961c30'	System	31 Oct 2020 20:35:31
User entered 'No interference with activity (1)'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '30445385-aed6-4efb-a830-312e62961c30' User entered '31 Oct 2020 15:35'	System	31 Oct 2020 20:35:31
	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:28:40



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Oct 2020 19:03:28
User entered 'Day 55'	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b21ba6e7-1cd7-4594-a2a5-aad4a29acbda'	System	01 Nov 2020 17:32:10
User entered 'No interference with activity (1)'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b21ba6e7-1cd7-4594-a2a5-aad4a29acbda' User entered '01 Nov 2020 12:32'	System	01 Nov 2020 17:32:10
	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Oct 2020 20:35:31
User entered 'Day 56'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ffa81b0d-1a72-433e-9076-176ea5b31fle' User entered 'No interference with activity (1)'	System	02 Nov 2020 19:20:32
	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ffa81b0d-1a72-433e-9076-176ea5b31fle' User entered '02 Nov 2020 14:20'	System	02 Nov 2020 19:20:32
	System	02 Nov 2020 19:20:32



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Nov 2020 17:32:10
User entered 'Day 57'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:07:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '04f738ab-686c-4049-a5cd-bf184eb9f771'	System	03 Nov 2020 18:08:07
User entered 'No interference with activity (1)'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '04f738ab-686c-4049-a5cd-bf184eb9f771'	System	03 Nov 2020 18:08:07
User entered '03 Nov 2020 12:08'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Nov 2020 19:20:32
User entered 'Day 58'	System	02 Nov 2020 19:20:32



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '06853e2c-4caf-43e4-bbb4-51a1f5e95346'	System	04 Nov 2020 18:00:42
User entered 'No interference with activity (1)'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '06853e2c-4caf-43e4-bbb4-51a1f5e95346'	System	04 Nov 2020 18:00:42
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Nov 2020 18:08:07
User entered 'Day 59'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '03f931b2-c4d7-4d40-a3c1-f6c1b3876cfd'	System	05 Nov 2020 18:23:43
User entered 'No interference with activity (1)'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '03f931b2-c4d7-4d40-a3c1-f6c1b3876cfd' User entered '05 Nov 2020 12:23'	System	05 Nov 2020 18:23:43
	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:08:07



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Nov 2020 18:00:42
User entered 'Day 60'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8d4911a2-cee2-4450-ab09-c07f150f164c'	System	06 Nov 2020 18:25:18
User entered 'No interference with activity (1)'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8d4911a2-cee2-4450-ab09-c07f150f164c' User entered '06 Nov 2020 12:25'	System	06 Nov 2020 18:25:18
	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Nov 2020 18:23:43
User entered 'Day 61'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5dec039c-76e0-447f-a2f2-0068e6e3dacf'	System	07 Nov 2020 18:06:26
User entered 'No interference with activity (1)'	System	07 Nov 2020 18:06:26



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5dec039c-76e0-447f-a2f2-0068e6e3dacf' User entered '07 Nov 2020 12:06'	System	07 Nov 2020 18:06:26
	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Nov 2020 18:25:18
User entered 'Day 62'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2fac4e1a-ca7a-48d8-8374-a411fb477384'	System	09 Nov 2020 12:16:36
User entered 'No interference with activity (1)'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2fac4e1a-ca7a-48d8-8374-a411fb477384' User entered '09 Nov 2020 06:16'	System	09 Nov 2020 12:16:36
	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 18:25:18



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Nov 2020 18:06:26
User entered 'Day 63'	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'da4a9ea7-c77b-4c43-a5cc-f96d6ce56ff9'	System	09 Nov 2020 18:21:09
User entered 'No interference with activity (1)'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'da4a9ea7-c77b-4c43-a5cc-f96d6ce56ff9'	System	09 Nov 2020 18:21:09
User entered '09 Nov 2020 12:21'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 12:16:36
User entered 'Day 64'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'deb2be30-6e23-46fc-a9e9-bbcac27b8aef' User entered 'No interference with activity (1)'	System	10 Nov 2020 18:03:25
	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'deb2be30-6e23-46fc-a9e9-bbcac27b8aef' User entered '10 Nov 2020 12:03'	System	10 Nov 2020 18:03:25
	System	10 Nov 2020 18:03:25



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 18:21:09
User entered 'Day 65'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '403f1497-4158-487b-aa58-9b7d29153d4c'	System	11 Nov 2020 18:00:27
User entered 'No interference with activity (1)'	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '403f1497-4158-487b-aa58-9b7d29153d4c' User entered '11 Nov 2020 12:00'	System	11 Nov 2020 18:00:27
	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Nov 2020 18:03:25
User entered 'Day 66'	System	10 Nov 2020 18:03:25



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '23cb1b35-b3b3-459b-bebf-b4441e3fd022'	System	12 Nov 2020 18:00:28
User entered 'No interference with activity (1)'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '23cb1b35-b3b3-459b-bebf-b4441e3fd022'	System	12 Nov 2020 18:00:28
User entered '12 Nov 2020 12:00'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Nov 2020 18:00:27
User entered 'Day 67'	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:37:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3b3765ca-3895-4b40-afc0-0b665b4ef899'	System	13 Nov 2020 18:38:05
User entered 'No interference with activity (1)'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3b3765ca-3895-4b40-afc0-0b665b4ef899'	System	13 Nov 2020 18:38:05
User entered '13 Nov 2020 12:38'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 18:00:27



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Nov 2020 18:00:28
User entered 'Day 68'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd720c5cc-1062-4d52-ab90-e0914e5c6f0d'	System	15 Nov 2020 09:46:57
User entered 'No interference with activity (1)'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd720c5cc-1062-4d52-ab90-e0914e5c6f0d' User entered '14 Nov 2020 12:33'	System	15 Nov 2020 09:46:57
	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Nov 2020 18:38:05
User entered 'Day 69'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c16c5238-10b2-488d-8f06-54737a9f6647'	System	15 Nov 2020 18:00:28
User entered 'No interference with activity (1)'	System	15 Nov 2020 18:00:28



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c16c5238-10b2-488d-8f06-54737a9f6647'	System	15 Nov 2020 18:00:28
User entered '15 Nov 2020 12:00'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 09:46:57
User entered 'Day 70'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5c59f6b1-5cdf-49c2-932c-057853df3756'	System	16 Nov 2020 18:00:22
User entered 'No interference with activity (1)'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5c59f6b1-5cdf-49c2-932c-057853df3756'	System	16 Nov 2020 18:00:22
User entered '16 Nov 2020 12:00'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 09:46:57



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 18:00:28
User entered 'Day 71'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bc3a7c4b-5325-4fb4-965d-d3c486e26bbb'	System	17 Nov 2020 23:33:22
User entered 'No interference with activity (1)'	System	17 Nov 2020 23:33:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bc3a7c4b-5325-4fb4-965d-d3c486e26bbb' User entered '17 Nov 2020 17:33'	System	17 Nov 2020 23:33:22
	System	17 Nov 2020 23:33:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Nov 2020 18:00:22
User entered 'Day 72'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:27:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '760038c8-7444-4758-afe0-961bdde79c5e' User entered 'None (0)'	System	18 Nov 2020 22:27:47
	System	18 Nov 2020 22:27:47

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:27:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '760038c8-7444-4758-afe0-961bdde79c5e' User entered '18 Nov 2020 16:27'	System	18 Nov 2020 22:27:47
	System	18 Nov 2020 22:27:47



US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Sep 2020 19:23:06
User entered 'Day 8'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b8e2b2c-e2d0-4da3-b2e7-3c9bdd1e0137'	System	15 Sep 2020 17:17:13
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:17:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b8e2b2c-e2d0-4da3-b2e7-3c9bdd1e0137'	System	15 Sep 2020 17:17:13
User entered '15 Sep 2020 12:17'	System	15 Sep 2020 17:17:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Sep 2020 17:13:17
User entered 'Day 9'	System	14 Sep 2020 17:13:17



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '37e424bc-70d5-403c-bb70-c5d925a35d1d'	System	16 Sep 2020 17:00:53
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '37e424bc-70d5-403c-bb70-c5d925a35d1d' User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:53
	System	16 Sep 2020 17:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Sep 2020 17:17:13
User entered 'Day 10'	System	15 Sep 2020 17:17:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:00:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '14806c5a-80df-4845-b687-63293f0d353a'	System	17 Sep 2020 17:01:29
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:00:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '14806c5a-80df-4845-b687-63293f0d353a' User entered '17 Sep 2020 12:00'	System	17 Sep 2020 17:01:29
	System	17 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:17:13



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:17:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Sep 2020 17:00:53
User entered 'Day 11'	System	16 Sep 2020 17:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2bb56b43-1d58-4cc2-943e-ea9d3baf1f02'	System	19 Sep 2020 11:10:13
User entered 'No interference with activity (1)'	System	19 Sep 2020 11:10:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2bb56b43-1d58-4cc2-943e-ea9d3baf1f02'	System	19 Sep 2020 11:10:13
User entered '19 Sep 2020 06:10'	System	19 Sep 2020 11:10:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Sep 2020 17:01:29
User entered 'Day 12'	System	17 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fd14b02e-1ed3-40c5-8a1a-bbff7cc0dfe1'	System	19 Sep 2020 17:00:26
User entered 'No interference with activity (1)'	System	19 Sep 2020 17:00:26



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fd14b02e-1ed3-40c5-8a1a-bbff7cc0dfe1' User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:00:26
	System	19 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 11:10:13
User entered 'Day 13'	System	19 Sep 2020 11:10:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e65a027-07f6-4b2a-8c43-fd6b3cdeed6c'	System	20 Sep 2020 17:00:26
User entered 'No interference with activity (1)'	System	20 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e65a027-07f6-4b2a-8c43-fd6b3cdeed6c'	System	20 Sep 2020 17:00:26
User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 11:10:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 11:10:13



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 17:00:26
User entered 'Day 14'	System	19 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ad2a8ef-e779-44c9-8f39-e79e6d1f459f'	System	21 Sep 2020 17:03:18
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:03:18

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ad2a8ef-e779-44c9-8f39-e79e6d1f459f' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:18
	System	21 Sep 2020 17:03:18

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Sep 2020 17:00:26
User entered 'Day 15'	System	20 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '020b70c1-7c13-44cd-8844-6de6211303d4'	System	22 Sep 2020 17:09:30
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:09:30

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '020b70c1-7c13-44cd-8844-6de6211303d4'	System	22 Sep 2020 17:09:30
User entered '22 Sep 2020 12:09'	System	22 Sep 2020 17:09:30



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Sep 2020 17:03:18
User entered 'Day 16'	System	21 Sep 2020 17:03:18

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '08a2278b-83ac-429a-a64f-0f5738b68b94'	System	24 Sep 2020 10:25:24
User entered 'No interference with activity (1)'	System	24 Sep 2020 10:25:24

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '08a2278b-83ac-429a-a64f-0f5738b68b94' User entered '24 Sep 2020 05:25'	System	24 Sep 2020 10:25:24
	System	24 Sep 2020 10:25:24

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:03:18

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:03:18

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Sep 2020 17:09:30
User entered 'Day 17'	System	22 Sep 2020 17:09:30



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b42f81e8-8576-494f-ae24-f58df8a62a68'	System	24 Sep 2020 17:15:13
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:15:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b42f81e8-8576-494f-ae24-f58df8a62a68' User entered '24 Sep 2020 12:15'	System	24 Sep 2020 17:15:13
	System	24 Sep 2020 17:15:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:09:30

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:09:30

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 10:25:24
User entered 'Day 18'	System	24 Sep 2020 10:25:24

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:00:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8c9ebc32-4c64-4ae9-80fe-ce7ac222fa13'	System	25 Sep 2020 17:02:15
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:02:15

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:01:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8c9ebc32-4c64-4ae9-80fe-ce7ac222fa13' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:15
	System	25 Sep 2020 17:02:15

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:25:24



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:25:24

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 17:15:13
User entered 'Day 19'	System	24 Sep 2020 17:15:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '706fb355-7727-4f60-9456-57f0c59dc311'	System	26 Sep 2020 17:00:56
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '706fb355-7727-4f60-9456-57f0c59dc311' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 17:00:56
	System	26 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:15:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:15:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Sep 2020 17:02:15
User entered 'Day 20'	System	25 Sep 2020 17:02:15

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8c9f1f65-3779-4b6c-a656-6bc1bb27fe2d'	System	28 Sep 2020 11:02:32
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:02:32



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8c9f1f65-3779-4b6c-a656-6bc1bb27fe2d' User entered '28 Sep 2020 06:02'	System	28 Sep 2020 11:02:32
	System	28 Sep 2020 11:02:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:02:15

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:02:15

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Sep 2020 17:00:56
User entered 'Day 21'	System	26 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '40ba461a-e12e-412a-a6aa-2703620d2fb6'	System	28 Sep 2020 17:03:57
User entered 'No interference with activity (1)'	System	28 Sep 2020 17:03:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '40ba461a-e12e-412a-a6aa-2703620d2fb6' User entered '28 Sep 2020 12:03'	System	28 Sep 2020 17:03:57
	System	28 Sep 2020 17:03:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:56

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:56



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 11:02:32
User entered 'Day 22'	System	28 Sep 2020 11:02:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e0d09dab-6b27-47b5-ab85-62ae998ed9cb'	System	29 Sep 2020 17:06:29
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:06:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e0d09dab-6b27-47b5-ab85-62ae998ed9cb' User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:06:29
	System	29 Sep 2020 17:06:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:02:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:02:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 17:03:57
User entered 'Day 23'	System	28 Sep 2020 17:03:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '58ad6fc8-bfad-4167-a693-ee2ddbf2e237'	System	30 Sep 2020 17:20:22
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:20:22

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '58ad6fc8-bfad-4167-a693-ee2ddbf2e237'	System	30 Sep 2020 17:20:22
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:20:22



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:03:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:03:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Sep 2020 17:06:29
User entered 'Day 24'	System	29 Sep 2020 17:06:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:39:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3c2dfe28-522f-49ff-b9bf-6d1bda44b9fe'	System	01 Oct 2020 19:40:08
User entered 'No interference with activity (1)'	System	01 Oct 2020 19:40:08

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:39:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3c2dfe28-522f-49ff-b9bf-6d1bda44b9fe' User entered '01 Oct 2020 14:39'	System	01 Oct 2020 19:40:08
	System	01 Oct 2020 19:40:08

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:06:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:06:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Sep 2020 17:20:22
User entered 'Day 25'	System	30 Sep 2020 17:20:22



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:02:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9ec078fb-be00-4933-9253-dd74efb98adf'	System	02 Oct 2020 17:04:13
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:04:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:04:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9ec078fb-be00-4933-9253-dd74efb98adf' User entered '02 Oct 2020 12:04'	System	02 Oct 2020 17:04:13
	System	02 Oct 2020 17:04:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:20:22

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:20:22

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Oct 2020 19:40:08
User entered 'Day 26'	System	01 Oct 2020 19:40:08

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '39995c59-f3cb-4da8-96b5-52381eb9f686'	System	04 Oct 2020 10:59:33
User entered 'No interference with activity (1)'	System	04 Oct 2020 10:59:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '39995c59-f3cb-4da8-96b5-52381eb9f686' User entered '04 Oct 2020 05:59'	System	04 Oct 2020 10:59:33
	System	04 Oct 2020 10:59:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:40:08



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:40:08

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Oct 2020 17:04:13
User entered 'Day 27'	System	02 Oct 2020 17:04:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ba6522b5-9f4e-4821-bbb8-e69b3af2fa05'	System	04 Oct 2020 17:00:39
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ba6522b5-9f4e-4821-bbb8-e69b3af2fa05'	System	04 Oct 2020 17:00:39
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:04:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:04:13

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 10:59:33
User entered 'Day 28'	System	04 Oct 2020 10:59:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:12:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7f8bece2-8032-4639-9bda-91fcad35d8c5'	System	05 Oct 2020 17:12:59
User entered 'No interference with activity (1)'	System	05 Oct 2020 17:12:59



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:12:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7f8bece2-8032-4639-9bda-91fcad35d8c5' User entered '05 Oct 2020 12:12'	System	05 Oct 2020 17:12:59
	System	05 Oct 2020 17:12:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 10:59:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 10:59:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 17:00:39
User entered 'Day 29'	System	04 Oct 2020 17:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:43:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '48553dd0-c1d9-45be-97e0-37f191c51cd8'	System	06 Oct 2020 17:43:59
User entered 'No interference with activity (1)'	System	06 Oct 2020 17:43:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:43:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '48553dd0-c1d9-45be-97e0-37f191c51cd8'	System	06 Oct 2020 17:43:59
User entered '06 Oct 2020 12:43'	System	06 Oct 2020 17:43:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:00:39



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Oct 2020 17:12:59
User entered 'Day 30'	System	05 Oct 2020 17:12:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '77983274-5fec-4808-9aa8-723857ca2466'	System	07 Oct 2020 17:36:42
User entered 'No interference with activity (1)'	System	07 Oct 2020 17:36:42

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '77983274-5fec-4808-9aa8-723857ca2466'	System	07 Oct 2020 17:36:42
User entered '07 Oct 2020 12:36'	System	07 Oct 2020 17:36:42

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:12:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:12:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Oct 2020 17:43:59
User entered 'Day 31'	System	06 Oct 2020 17:43:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f5846b9-e094-4a1d-b0c5-f2b6337a04e9'	System	08 Oct 2020 18:00:39
User entered 'No interference with activity (1)'	System	08 Oct 2020 18:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f5846b9-e094-4a1d-b0c5-f2b6337a04e9' User entered '08 Oct 2020 13:00'	System	08 Oct 2020 18:00:39
	System	08 Oct 2020 18:00:39



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:43:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:43:59

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Oct 2020 17:36:42
User entered 'Day 32'	System	07 Oct 2020 17:36:42

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9cd82eb0-8b09-43df-8b07-29cc416b0724'	System	09 Oct 2020 17:00:38
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9cd82eb0-8b09-43df-8b07-29cc416b0724' User entered '09 Oct 2020 12:00'	System	09 Oct 2020 17:00:38
	System	09 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:36:42

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:36:42

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Oct 2020 18:00:39
User entered 'Day 33'	System	08 Oct 2020 18:00:39



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cc2be796-f53a-4dc6-9c4d-470eb5f70592'	System	10 Oct 2020 17:24:44
User entered 'No interference with activity (1)'	System	10 Oct 2020 17:24:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cc2be796-f53a-4dc6-9c4d-470eb5f70592'	System	10 Oct 2020 17:24:44
User entered '10 Oct 2020 12:24'	System	10 Oct 2020 17:24:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:00:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Oct 2020 17:00:38
User entered 'Day 34'	System	09 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53cd41c2-3cfe-4930-ab65-f846f06f3e0b' User entered 'Some interference with activity (2)'	System	11 Oct 2020 17:47:05
	System	11 Oct 2020 17:47:05

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53cd41c2-3cfe-4930-ab65-f846f06f3e0b'	System	11 Oct 2020 17:47:05
User entered '11 Oct 2020 12:46'	System	11 Oct 2020 17:47:05

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:38



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Oct 2020 17:24:44
User entered 'Day 35'	System	10 Oct 2020 17:24:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e84f4ec-2c16-4b05-8cb5-c5f4c7cfc361'	System	12 Oct 2020 17:32:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 17:32:48

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8e84f4ec-2c16-4b05-8cb5-c5f4c7cfc361'	System	12 Oct 2020 17:32:48
User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:32:48

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:24:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:24:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Oct 2020 17:47:05
User entered 'Day 36'	System	11 Oct 2020 17:47:05

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '861f51bb-35f2-4911-bc86-a7be939d4ed6'	System	13 Oct 2020 17:07:52
User entered 'No interference with activity (1)'	System	13 Oct 2020 17:07:52



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '861f51bb-35f2-4911-bc86-a7be939d4ed6' User entered '13 Oct 2020 12:07'	System	13 Oct 2020 17:07:52
	System	13 Oct 2020 17:07:52

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 17:47:05

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 17:47:05

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Oct 2020 17:32:48
User entered 'Day 37'	System	12 Oct 2020 17:32:48

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f832bd2d-ff99-43f2-bcd3-d2ce11ae5fc3'	System	14 Oct 2020 17:01:44
User entered 'No interference with activity (1)'	System	14 Oct 2020 17:01:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f832bd2d-ff99-43f2-bcd3-d2ce11ae5fc3' User entered '14 Oct 2020 12:01'	System	14 Oct 2020 17:01:44
	System	14 Oct 2020 17:01:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 17:32:48

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 17:32:48



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Oct 2020 17:07:52
User entered 'Day 38'	System	13 Oct 2020 17:07:52

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c737c591-1f19-4234-93b1-d0b584cd81b0'	System	15 Oct 2020 17:01:23
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:01:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c737c591-1f19-4234-93b1-d0b584cd81b0' User entered '15 Oct 2020 12:01'	System	15 Oct 2020 17:01:23
	System	15 Oct 2020 17:01:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:07:52

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:07:52

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Oct 2020 17:01:44
User entered 'Day 39'	System	14 Oct 2020 17:01:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '234f444a-ea95-4d35-8615-213a19bb112c'	System	16 Oct 2020 17:01:39
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:01:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '234f444a-ea95-4d35-8615-213a19bb112c' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 17:01:39
	System	16 Oct 2020 17:01:39



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:01:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:01:44

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Oct 2020 17:01:23
User entered 'Day 40'	System	15 Oct 2020 17:01:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c81eb235-881e-4537-bd64-d2d9a4297152'	System	18 Oct 2020 14:15:51
User entered 'No interference with activity (1)'	System	18 Oct 2020 14:15:51

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c81eb235-881e-4537-bd64-d2d9a4297152'	System	18 Oct 2020 14:15:51
User entered '18 Oct 2020 09:15'	System	18 Oct 2020 14:15:51

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:01:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:01:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Oct 2020 17:01:39
User entered 'Day 41'	System	16 Oct 2020 17:01:39



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '97a00722-c66a-40da-a699-144495584c10'	System	18 Oct 2020 17:00:38
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '97a00722-c66a-40da-a699-144495584c10' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 17:00:38
	System	18 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:01:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:01:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 14:15:51
User entered 'Day 42'	System	18 Oct 2020 14:15:51

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f6c8868b-757e-487c-beb7-d3ad6bfb7aa3'	System	19 Oct 2020 17:13:23
User entered 'No interference with activity (1)'	System	19 Oct 2020 17:13:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f6c8868b-757e-487c-beb7-d3ad6bfb7aa3'	System	19 Oct 2020 17:13:23
User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 14:15:51



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 14:15:51

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 17:00:38
User entered 'Day 43'	System	18 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c6e2d118-8b5c-41ed-b923-aa537434b604'	System	20 Oct 2020 17:00:43
User entered 'No interference with activity (1)'	System	20 Oct 2020 17:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c6e2d118-8b5c-41ed-b923-aa537434b604' User entered '20 Oct 2020 12:00'	System	20 Oct 2020 17:00:43
	System	20 Oct 2020 17:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Oct 2020 17:13:23
User entered 'Day 44'	System	19 Oct 2020 17:13:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fb7f77e8-9b77-44e9-81d2-72ea6003d404'	System	22 Oct 2020 01:50:20
User entered 'No interference with activity (1)'	System	22 Oct 2020 01:50:20



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fb7f77e8-9b77-44e9-81d2-72ea6003d404'	System	22 Oct 2020 01:50:20
User entered '21 Oct 2020 20:50'	System	22 Oct 2020 01:50:20

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:23

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Oct 2020 17:00:43
User entered 'Day 45'	System	20 Oct 2020 17:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '581aced9-3227-4478-9440-3d56f9e9ba29'	System	23 Oct 2020 12:19:16
User entered 'No interference with activity (1)'	System	23 Oct 2020 12:19:16

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '581aced9-3227-4478-9440-3d56f9e9ba29' User entered '22 Oct 2020 12:00'	System	23 Oct 2020 12:19:16
	System	23 Oct 2020 12:19:16

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:00:43



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Oct 2020 01:50:20
User entered 'Day 46'	System	22 Oct 2020 01:50:20

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '424ace4c-ca0f-4030-86da-19ea8d54194a'	System	23 Oct 2020 17:29:28
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:29:28

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '424ace4c-ca0f-4030-86da-19ea8d54194a' User entered '23 Oct 2020 12:29'	System	23 Oct 2020 17:29:28
	System	23 Oct 2020 17:29:28

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:50:20

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:50:20

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 12:19:16
User entered 'Day 47'	System	23 Oct 2020 12:19:16

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:10:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '34e0c375-4627-4327-8cf9-e6b0bb04a5a1'	System	24 Oct 2020 17:11:04
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:11:04

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:11:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '34e0c375-4627-4327-8cf9-e6b0bb04a5a1' User entered '24 Oct 2020 12:11'	System	24 Oct 2020 17:11:04
	System	24 Oct 2020 17:11:04



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:19:16

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:19:16

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 17:29:28
User entered 'Day 48'	System	23 Oct 2020 17:29:28

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bff816dc-b438-457d-8e08-64fccd773649'	System	26 Oct 2020 10:52:54
User entered 'No interference with activity (1)'	System	26 Oct 2020 10:52:54

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bff816dc-b438-457d-8e08-64fccd773649' User entered '26 Oct 2020 05:52'	System	26 Oct 2020 10:52:54
	System	26 Oct 2020 10:52:54

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:29:28

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:29:28

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Oct 2020 17:11:04
User entered 'Day 49'	System	24 Oct 2020 17:11:04



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e35ac83-9983-48b6-9ce1-5b64cd874b65'	System	26 Oct 2020 17:13:06
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:13:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e35ac83-9983-48b6-9ce1-5b64cd874b65' User entered '26 Oct 2020 12:13'	System	26 Oct 2020 17:13:06
	System	26 Oct 2020 17:13:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:11:04

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:11:04

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 10:52:54
User entered 'Day 50'	System	26 Oct 2020 10:52:54

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8d9387e-1b28-4f3c-a082-c07c08207af7'	System	27 Oct 2020 17:01:06
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:01:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a8d9387e-1b28-4f3c-a082-c07c08207af7' User entered '27 Oct 2020 12:00'	System	27 Oct 2020 17:01:06
	System	27 Oct 2020 17:01:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 10:52:54



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 10:52:54

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 17:13:06
User entered 'Day 51'	System	26 Oct 2020 17:13:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50e13594-6fbf-4289-9421-5547f2fc4543'	System	28 Oct 2020 17:06:21
User entered 'No interference with activity (1)'	System	28 Oct 2020 17:06:21

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50e13594-6fbf-4289-9421-5547f2fc4543' User entered '28 Oct 2020 12:04'	System	28 Oct 2020 17:06:21
	System	28 Oct 2020 17:06:21

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:13:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:13:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Oct 2020 17:01:06
User entered 'Day 52'	System	27 Oct 2020 17:01:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7cb4601a-9bf8-4e36-a9de-86e369afbf94'	System	29 Oct 2020 17:28:46
User entered 'No interference with activity (1)'	System	29 Oct 2020 17:28:46



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7cb4601a-9bf8-4e36-a9de-86e369afbf94'	System	29 Oct 2020 17:28:46
User entered '29 Oct 2020 12:28'	System	29 Oct 2020 17:28:46

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:01:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:01:06

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Oct 2020 17:06:21
User entered 'Day 53'	System	28 Oct 2020 17:06:21

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4d36af46-5bf9-4ec6-8e7e-12d7d259de95'	System	30 Oct 2020 19:03:41
User entered 'No interference with activity (1)'	System	30 Oct 2020 19:03:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4d36af46-5bf9-4ec6-8e7e-12d7d259de95' User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:03:41
	System	30 Oct 2020 19:03:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:06:21

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:06:21



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Oct 2020 17:28:46
User entered 'Day 54'	System	29 Oct 2020 17:28:46

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '73277d15-fecd-4cbc-9aec-e8f53b9edfa9'	System	31 Oct 2020 20:35:39
User entered 'No interference with activity (1)'	System	31 Oct 2020 20:35:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '73277d15-fecd-4cbc-9aec-e8f53b9edfa9' User entered '31 Oct 2020 15:35'	System	31 Oct 2020 20:35:39
	System	31 Oct 2020 20:35:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:28:46

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:28:46

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Oct 2020 19:03:41
User entered 'Day 55'	System	30 Oct 2020 19:03:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f20f49a-f350-40f5-b426-e006a8f3b7f5'	System	01 Nov 2020 17:32:14
User entered 'No interference with activity (1)'	System	01 Nov 2020 17:32:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6f20f49a-f350-40f5-b426-e006a8f3b7f5'	System	01 Nov 2020 17:32:14
User entered '01 Nov 2020 12:32'	System	01 Nov 2020 17:32:14



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:03:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:03:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Oct 2020 20:35:39
User entered 'Day 56'	System	31 Oct 2020 20:35:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '309c3156-93a8-460c-a5d1-e69adbba916a'	System	02 Nov 2020 19:20:41
User entered 'No interference with activity (1)'	System	02 Nov 2020 19:20:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '309c3156-93a8-460c-a5d1-e69adbba916a' User entered '02 Nov 2020 14:20'	System	02 Nov 2020 19:20:41
	System	02 Nov 2020 19:20:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 20:35:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 20:35:39

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Nov 2020 17:32:14
User entered 'Day 57'	System	01 Nov 2020 17:32:14



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0ed9e075-fe07-47ab-a142-1c7c438b91da'	System	03 Nov 2020 18:08:14
User entered 'No interference with activity (1)'	System	03 Nov 2020 18:08:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0ed9e075-fe07-47ab-a142-1c7c438b91da' User entered '03 Nov 2020 12:08'	System	03 Nov 2020 18:08:14
	System	03 Nov 2020 18:08:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:32:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:32:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Nov 2020 19:20:41
User entered 'Day 58'	System	02 Nov 2020 19:20:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '16818c59-c098-4387-8c51-b91ea82e4094'	System	04 Nov 2020 18:00:49
User entered 'No interference with activity (1)'	System	04 Nov 2020 18:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '16818c59-c098-4387-8c51-b91ea82e4094' User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:49
	System	04 Nov 2020 18:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 19:20:41



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 19:20:41

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Nov 2020 18:08:14
User entered 'Day 59'	System	03 Nov 2020 18:08:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a862e03f-8a2a-4444-9229-413a6dc39408'	System	05 Nov 2020 18:23:53
User entered 'No interference with activity (1)'	System	05 Nov 2020 18:23:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a862e03f-8a2a-4444-9229-413a6dc39408' User entered '05 Nov 2020 12:23'	System	05 Nov 2020 18:23:53
	System	05 Nov 2020 18:23:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:08:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:08:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Nov 2020 18:00:49
User entered 'Day 60'	System	04 Nov 2020 18:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '71292c43-c8f5-4dfd-a183-be13a4c97dd3'	System	06 Nov 2020 18:25:29
User entered 'No interference with activity (1)'	System	06 Nov 2020 18:25:29



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '71292c43-c8f5-4dfd-a183-be13a4c97dd3' User entered '06 Nov 2020 12:25'	System	06 Nov 2020 18:25:29
	System	06 Nov 2020 18:25:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Nov 2020 18:23:53
User entered 'Day 61'	System	05 Nov 2020 18:23:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3466c3d1-d84e-405f-8adb-2034f3f87943'	System	07 Nov 2020 18:06:34
User entered 'No interference with activity (1)'	System	07 Nov 2020 18:06:34

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3466c3d1-d84e-405f-8adb-2034f3f87943'	System	07 Nov 2020 18:06:34
User entered '07 Nov 2020 12:06'	System	07 Nov 2020 18:06:34

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:23:53

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:23:53



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Nov 2020 18:25:29
User entered 'Day 62'	System	06 Nov 2020 18:25:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0eabb0b7-24b9-4576-8b68-70b6c85a7f0f'	System	09 Nov 2020 12:16:43
User entered 'No interference with activity (1)'	System	09 Nov 2020 12:16:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0eabb0b7-24b9-4576-8b68-70b6c85a7f0f' User entered '09 Nov 2020 06:16'	System	09 Nov 2020 12:16:43
	System	09 Nov 2020 12:16:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 18:25:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 18:25:29

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Nov 2020 18:06:34
User entered 'Day 63'	System	07 Nov 2020 18:06:34

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '33d5cc3d-60f5-475e-b493-09e11dbe8427'	System	09 Nov 2020 18:21:17
User entered 'No interference with activity (1)'	System	09 Nov 2020 18:21:17

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '33d5cc3d-60f5-475e-b493-09e11dbe8427' User entered '09 Nov 2020 12:21'	System	09 Nov 2020 18:21:17
	System	09 Nov 2020 18:21:17



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:06:34

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:06:34

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 12:16:43
User entered 'Day 64'	System	09 Nov 2020 12:16:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b335f6a9-8f43-4e72-aff0-11da9ccb77d9'	System	10 Nov 2020 18:03:33
User entered 'No interference with activity (1)'	System	10 Nov 2020 18:03:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b335f6a9-8f43-4e72-aff0-11da9ccb77d9' User entered '10 Nov 2020 12:03'	System	10 Nov 2020 18:03:33
	System	10 Nov 2020 18:03:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 12:16:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 12:16:43

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 18:21:17
User entered 'Day 65'	System	09 Nov 2020 18:21:17



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3c7d8b99-70d5-4f24-a62f-769ee2bceec'	System	11 Nov 2020 18:00:40
User entered 'No interference with activity (1)'	System	11 Nov 2020 18:00:40

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3c7d8b99-70d5-4f24-a62f-769ee2bceec'	System	11 Nov 2020 18:00:40
User entered '11 Nov 2020 12:00'	System	11 Nov 2020 18:00:40

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:21:17

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:21:17

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Nov 2020 18:03:33
User entered 'Day 66'	System	10 Nov 2020 18:03:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6ebf2b5-460c-4f3d-bd8e-558582064cc6'	System	12 Nov 2020 18:00:33
User entered 'No interference with activity (1)'	System	12 Nov 2020 18:00:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6ebf2b5-460c-4f3d-bd8e-558582064cc6'	System	12 Nov 2020 18:00:33
User entered '12 Nov 2020 12:00'	System	12 Nov 2020 18:00:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:03:33



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:03:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Nov 2020 18:00:40
User entered 'Day 67'	System	11 Nov 2020 18:00:40

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c52822d3-fa6c-4a04-9504-cd9ff3d15f9d'	System	13 Nov 2020 18:38:14
User entered 'No interference with activity (1)'	System	13 Nov 2020 18:38:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c52822d3-fa6c-4a04-9504-cd9ff3d15f9d' User entered '13 Nov 2020 12:38'	System	13 Nov 2020 18:38:14
	System	13 Nov 2020 18:38:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 18:00:40

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 18:00:40

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Nov 2020 18:00:33
User entered 'Day 68'	System	12 Nov 2020 18:00:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cc5f8312-fa4f-4d9f-b2db-3ec7cb1d49ac'	System	15 Nov 2020 09:46:57
User entered 'No interference with activity (1)'	System	15 Nov 2020 09:46:57



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cc5f8312-fa4f-4d9f-b2db-3ec7cb1d49ac'	System	15 Nov 2020 09:46:57
User entered '14 Nov 2020 12:33'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:00:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:00:33

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Nov 2020 18:38:14
User entered 'Day 69'	System	13 Nov 2020 18:38:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '61f16803-b528-4471-9802-35a1919174d9'	System	15 Nov 2020 18:00:38
User entered 'No interference with activity (1)'	System	15 Nov 2020 18:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '61f16803-b528-4471-9802-35a1919174d9'	System	15 Nov 2020 18:00:38
User entered '15 Nov 2020 12:00'	System	15 Nov 2020 18:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 18:38:14

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 18:38:14



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 09:46:57
User entered 'Day 70'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2a0f8975-44d6-4043-8de2-d1c75b9ac2fc'	System	16 Nov 2020 18:00:32
User entered 'No interference with activity (1)'	System	16 Nov 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2a0f8975-44d6-4043-8de2-d1c75b9ac2fc' User entered '16 Nov 2020 12:00'	System	16 Nov 2020 18:00:32
	System	16 Nov 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 18:00:38
User entered 'Day 71'	System	15 Nov 2020 18:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '18c9dded-c80f-4073-a3d6-39b8d55f62dc'	System	17 Nov 2020 23:33:32
User entered 'No interference with activity (1)'	System	17 Nov 2020 23:33:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '18c9dded-c80f-4073-a3d6-39b8d55f62dc' User entered '17 Nov 2020 17:33'	System	17 Nov 2020 23:33:32
	System	17 Nov 2020 23:33:32



US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Nov 2020 18:00:32
User entered 'Day 72'	System	16 Nov 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:27:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '46c85060-1a98-48f7-8d15-de5b0e0b8953' User entered 'None (0)'	System	18 Nov 2020 22:27:58
	System	18 Nov 2020 22:27:58

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:27:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '46c85060-1a98-48f7-8d15-de5b0e0b8953' User entered '18 Nov 2020 16:27'	System	18 Nov 2020 22:27:58
	System	18 Nov 2020 22:27:58

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Sep 2020 19:23:06
User entered 'Day 8'	System	13 Sep 2020 19:23:06



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '12309cb6-f041-4d37-8463-014acdd615ed'	System	15 Sep 2020 17:17:22
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:17:22

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '12309cb6-f041-4d37-8463-014acdd615ed' User entered '15 Sep 2020 12:17'	System	15 Sep 2020 17:17:22
	System	15 Sep 2020 17:17:22

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Sep 2020 17:13:17
User entered 'Day 9'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '75d29158-213f-4f5a-a408-45ba1087052f' User entered 'No interference with activity (1)'	System	16 Sep 2020 17:01:18
	System	16 Sep 2020 17:01:18

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '75d29158-213f-4f5a-a408-45ba1087052f' User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:01:18
	System	16 Sep 2020 17:01:18

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:13:17



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Sep 2020 17:17:22
User entered 'Day 10'	System	15 Sep 2020 17:17:22

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:00:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7fe5644c-87f2-40ce-bffb-0bdf72ac727a'	System	17 Sep 2020 17:01:47
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:01:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:01:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7fe5644c-87f2-40ce-bffb-0bdf72ac727a' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:01:47
	System	17 Sep 2020 17:01:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:17:22

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:17:22

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Sep 2020 17:01:18
User entered 'Day 11'	System	16 Sep 2020 17:01:18

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '821d626c-15a2-4ae2-a4a4-9a2596721435'	System	19 Sep 2020 11:10:29
User entered 'No interference with activity (1)'	System	19 Sep 2020 11:10:29



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '821d626c-15a2-4ae2-a4a4-9a2596721435' User entered '19 Sep 2020 06:10'	System	19 Sep 2020 11:10:29
	System	19 Sep 2020 11:10:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:01:18

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:01:18

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Sep 2020 17:01:47
User entered 'Day 12'	System	17 Sep 2020 17:01:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '79189913-02e1-44d9-87b8-3fbb3e43d09c'	System	19 Sep 2020 17:00:38
User entered 'No interference with activity (1)'	System	19 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '79189913-02e1-44d9-87b8-3fbb3e43d09c'	System	19 Sep 2020 17:00:38
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:01:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:01:47



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 11:10:29
User entered 'Day 13'	System	19 Sep 2020 11:10:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '43995417-daee-44c6-b13a-1b7f9c0385bd'	System	20 Sep 2020 17:00:38
User entered 'No interference with activity (1)'	System	20 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '43995417-daee-44c6-b13a-1b7f9c0385bd' User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:38
	System	20 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 11:10:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 11:10:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 17:00:38
User entered 'Day 14'	System	19 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1d318df-9a32-47f9-9ec4-d3eff2641278'	System	21 Sep 2020 17:03:35
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:03:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c1d318df-9a32-47f9-9ec4-d3eff2641278'	System	21 Sep 2020 17:03:35
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:35



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Sep 2020 17:00:38
User entered 'Day 15'	System	20 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cabd5c34-0225-4bf2-927e-0d2ee86726d7'	System	22 Sep 2020 17:09:35
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:09:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cabd5c34-0225-4bf2-927e-0d2ee86726d7' User entered '22 Sep 2020 12:09'	System	22 Sep 2020 17:09:35
	System	22 Sep 2020 17:09:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 17:00:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Sep 2020 17:03:35
User entered 'Day 16'	System	21 Sep 2020 17:03:35



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '91c49a3c-9bdc-4750-876f-2c2956b678be'	System	24 Sep 2020 10:25:31
User entered 'No interference with activity (1)'	System	24 Sep 2020 10:25:31

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '91c49a3c-9bdc-4750-876f-2c2956b678be' User entered '24 Sep 2020 05:25'	System	24 Sep 2020 10:25:31
	System	24 Sep 2020 10:25:31

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:03:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:03:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Sep 2020 17:09:35
User entered 'Day 17'	System	22 Sep 2020 17:09:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1ac099a5-4592-478c-bfd3-d25d61ddd434'	System	24 Sep 2020 17:15:20
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:15:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1ac099a5-4592-478c-bfd3-d25d61ddd434' User entered '24 Sep 2020 12:15'	System	24 Sep 2020 17:15:20
	System	24 Sep 2020 17:15:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:09:35



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:09:35

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 10:25:31
User entered 'Day 18'	System	24 Sep 2020 10:25:31

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:01:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bae13c51-2642-425d-aa6c-d2306371c1fe'	System	25 Sep 2020 17:02:43
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:02:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:01:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bae13c51-2642-425d-aa6c-d2306371c1fe' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:43
	System	25 Sep 2020 17:02:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:25:31

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:25:31

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 17:15:20
User entered 'Day 19'	System	24 Sep 2020 17:15:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b39ae354-2081-4863-bad1-e75ab4c2df60'	System	26 Sep 2020 17:01:13
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:01:13



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b39ae354-2081-4863-bad1-e75ab4c2df60'	System	26 Sep 2020 17:01:13
User entered '26 Sep 2020 12:00'	System	26 Sep 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:15:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:15:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Sep 2020 17:02:43
User entered 'Day 20'	System	25 Sep 2020 17:02:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6b9733c-80f9-4309-8e7c-73e11043a5cb'	System	28 Sep 2020 11:02:40
User entered 'Some interference with activity (2)'	System	28 Sep 2020 11:02:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6b9733c-80f9-4309-8e7c-73e11043a5cb' User entered '28 Sep 2020 06:02'	System	28 Sep 2020 11:02:40
	System	28 Sep 2020 11:02:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:02:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:02:43



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Sep 2020 17:01:13
User entered 'Day 21'	System	26 Sep 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4f4af584-b241-4b97-b8e7-0db2abf9b864'	System	28 Sep 2020 17:04:01
User entered 'No interference with activity (1)'	System	28 Sep 2020 17:04:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4f4af584-b241-4b97-b8e7-0db2abf9b864' User entered '28 Sep 2020 12:03'	System	28 Sep 2020 17:04:01
	System	28 Sep 2020 17:04:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 11:02:40
User entered 'Day 22'	System	28 Sep 2020 11:02:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8bacbd5f-771e-4e1e-8832-85bebcf912f6'	System	29 Sep 2020 17:06:36
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:06:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8bacbd5f-771e-4e1e-8832-85bebcf912f6'	System	29 Sep 2020 17:06:36
User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:06:36



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:02:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:02:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 17:04:01
User entered 'Day 23'	System	28 Sep 2020 17:04:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4f1a9dd1-f647-484b-9ad6-0b62074611c7'	System	30 Sep 2020 17:20:37
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:20:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4f1a9dd1-f647-484b-9ad6-0b62074611c7' User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:20:37
	System	30 Sep 2020 17:20:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:04:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:04:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Sep 2020 17:06:36
User entered 'Day 24'	System	29 Sep 2020 17:06:36



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:40:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fe882c67-e88a-4ad5-9906-6fc935f9d298'	System	01 Oct 2020 19:40:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 19:40:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:40:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fe882c67-e88a-4ad5-9906-6fc935f9d298'	System	01 Oct 2020 19:40:09
User entered '01 Oct 2020 14:40'	System	01 Oct 2020 19:40:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:06:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:06:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Sep 2020 17:20:37
User entered 'Day 25'	System	30 Sep 2020 17:20:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:04:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c706d5e2-8e08-4740-9684-a052ed1a5c02'	System	02 Oct 2020 17:05:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:05:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:04:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c706d5e2-8e08-4740-9684-a052ed1a5c02'	System	02 Oct 2020 17:05:43
User entered '02 Oct 2020 12:04'	System	02 Oct 2020 17:05:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:20:37



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:20:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Oct 2020 19:40:09
User entered 'Day 26'	System	01 Oct 2020 19:40:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1f1d69c5-4b53-496e-9fe1-541159b64f5f'	System	04 Oct 2020 10:59:38
User entered 'No interference with activity (1)'	System	04 Oct 2020 10:59:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1f1d69c5-4b53-496e-9fe1-541159b64f5f' User entered '04 Oct 2020 05:59'	System	04 Oct 2020 10:59:38
	System	04 Oct 2020 10:59:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:40:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:40:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Oct 2020 17:05:43
User entered 'Day 27'	System	02 Oct 2020 17:05:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7f248a09-e91e-47de-8320-e9d95cec12d9'	System	04 Oct 2020 17:00:47
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:00:47



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7f248a09-e91e-47de-8320-e9d95cec12d9'	System	04 Oct 2020 17:00:47
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:05:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:05:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 10:59:38
User entered 'Day 28'	System	04 Oct 2020 10:59:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:12:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0c1ad7c2-204e-4a2d-a2ec-533110d547dc'	System	05 Oct 2020 17:13:04
User entered 'No interference with activity (1)'	System	05 Oct 2020 17:13:04

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:13:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0c1ad7c2-204e-4a2d-a2ec-533110d547dc' User entered '05 Oct 2020 12:13'	System	05 Oct 2020 17:13:04
	System	05 Oct 2020 17:13:04

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 10:59:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 10:59:38



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 17:00:47
User entered 'Day 29'	System	04 Oct 2020 17:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:44:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50312623-8c80-4770-a567-b63b3de01557'	System	06 Oct 2020 17:44:10
User entered 'No interference with activity (1)'	System	06 Oct 2020 17:44:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:44:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50312623-8c80-4770-a567-b63b3de01557' User entered '06 Oct 2020 12:44'	System	06 Oct 2020 17:44:10
	System	06 Oct 2020 17:44:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Oct 2020 17:13:04
User entered 'Day 30'	System	05 Oct 2020 17:13:04

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c94a95e7-2355-4e43-aa17-3bad5d6f9321'	System	07 Oct 2020 17:36:49
User entered 'No interference with activity (1)'	System	07 Oct 2020 17:36:49

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:45', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c94a95e7-2355-4e43-aa17-3bad5d6f9321' User entered '07 Oct 2020 12:36'	System	07 Oct 2020 17:36:49
	System	07 Oct 2020 17:36:49



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:13:04

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:13:04

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Oct 2020 17:44:10
User entered 'Day 31'	System	06 Oct 2020 17:44:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3370e767-2160-4091-a6b9-b2f3f326ae30'	System	08 Oct 2020 18:00:44
User entered 'No interference with activity (1)'	System	08 Oct 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3370e767-2160-4091-a6b9-b2f3f326ae30' User entered '08 Oct 2020 13:00'	System	08 Oct 2020 18:00:44
	System	08 Oct 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:44:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:44:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Oct 2020 17:36:49
User entered 'Day 32'	System	07 Oct 2020 17:36:49



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c24144f0-1717-4ed6-aab2-2ca4a9a32797'	System	09 Oct 2020 17:01:01
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:01:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c24144f0-1717-4ed6-aab2-2ca4a9a32797' User entered '09 Oct 2020 12:00'	System	09 Oct 2020 17:01:01
	System	09 Oct 2020 17:01:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:36:49

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:36:49

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Oct 2020 18:00:44
User entered 'Day 33'	System	08 Oct 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6224f7c-3518-46c8-9ec4-60880bc3f57a' User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:24:54
	System	10 Oct 2020 17:24:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e6224f7c-3518-46c8-9ec4-60880bc3f57a' User entered '10 Oct 2020 12:24'	System	10 Oct 2020 17:24:54
	System	10 Oct 2020 17:24:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:00:44



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Oct 2020 17:01:01
User entered 'Day 34'	System	09 Oct 2020 17:01:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3fff22ea-ec3a-44b3-a016-9209acf7101c'	System	11 Oct 2020 17:47:10
User entered 'No interference with activity (1)'	System	11 Oct 2020 17:47:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:46:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3fff22ea-ec3a-44b3-a016-9209acf7101c' User entered '11 Oct 2020 12:46'	System	11 Oct 2020 17:47:10
	System	11 Oct 2020 17:47:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:01:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:01:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Oct 2020 17:24:54
User entered 'Day 35'	System	10 Oct 2020 17:24:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b3bf86a8-bd4a-4c49-9667-6b7f77532e59'	System	12 Oct 2020 17:32:52
User entered 'No interference with activity (1)'	System	12 Oct 2020 17:32:52



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b3bf86a8-bd4a-4c49-9667-6b7f77532e59'	System	12 Oct 2020 17:32:52
User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:32:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:24:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:24:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Oct 2020 17:47:10
User entered 'Day 36'	System	11 Oct 2020 17:47:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2b1a115e-1abf-4980-8c11-29dfe820918c'	System	13 Oct 2020 17:07:59
User entered 'No interference with activity (1)'	System	13 Oct 2020 17:07:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:07:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2b1a115e-1abf-4980-8c11-29dfe820918c' User entered '13 Oct 2020 12:07'	System	13 Oct 2020 17:07:59
	System	13 Oct 2020 17:07:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 17:47:10

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 17:47:10



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Oct 2020 17:32:52
User entered 'Day 37'	System	12 Oct 2020 17:32:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:13', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'afa351f5-a805-49c9-aeca-99cb02e3ea54'	System	14 Oct 2020 17:01:52
User entered 'No interference with activity (1)'	System	14 Oct 2020 17:01:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'afa351f5-a805-49c9-aeca-99cb02e3ea54' User entered '14 Oct 2020 12:01'	System	14 Oct 2020 17:01:52
	System	14 Oct 2020 17:01:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 17:32:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 17:32:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Oct 2020 17:07:59
User entered 'Day 38'	System	13 Oct 2020 17:07:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c4c36120-c799-42e4-8d10-084170d2067b'	System	15 Oct 2020 17:02:01
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:02:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c4c36120-c799-42e4-8d10-084170d2067b' User entered '15 Oct 2020 12:01'	System	15 Oct 2020 17:02:01
	System	15 Oct 2020 17:02:01



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:07:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:07:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Oct 2020 17:01:52
User entered 'Day 39'	System	14 Oct 2020 17:01:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b74608a8-3960-4ad6-80d4-3887d756e37a'	System	16 Oct 2020 17:01:48
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:01:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b74608a8-3960-4ad6-80d4-3887d756e37a' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 17:01:48
	System	16 Oct 2020 17:01:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:01:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:01:52

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Oct 2020 17:02:01
User entered 'Day 40'	System	15 Oct 2020 17:02:01



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1e3250de-153d-4b73-bc95-90e2c69a788b'	System	18 Oct 2020 14:15:59
User entered 'No interference with activity (1)'	System	18 Oct 2020 14:15:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:15:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1e3250de-153d-4b73-bc95-90e2c69a788b' User entered '18 Oct 2020 09:15'	System	18 Oct 2020 14:15:59
	System	18 Oct 2020 14:15:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:02:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:02:01

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Oct 2020 17:01:48
User entered 'Day 41'	System	16 Oct 2020 17:01:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '60954953-80a9-4a38-8e74-b80ae8cdad41'	System	18 Oct 2020 17:00:42
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '60954953-80a9-4a38-8e74-b80ae8cdad41' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 17:00:42
	System	18 Oct 2020 17:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:01:48



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:01:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 14:15:59
User entered 'Day 42'	System	18 Oct 2020 14:15:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'afe5d391-9f8a-4e8b-8187-253f3caciaa4d'	System	19 Oct 2020 17:13:37
User entered 'No interference with activity (1)'	System	19 Oct 2020 17:13:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'afe5d391-9f8a-4e8b-8187-253f3caciaa4d' User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:37
	System	19 Oct 2020 17:13:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 14:15:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 14:15:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 17:00:42
User entered 'Day 43'	System	18 Oct 2020 17:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '675caaf5-ac03-4e8d-8516-22937d0494a1'	System	20 Oct 2020 17:00:54
User entered 'No interference with activity (1)'	System	20 Oct 2020 17:00:54



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '675caaf5-ac03-4e8d-8516-22937d0494a1' User entered '20 Oct 2020 12:00'	System	20 Oct 2020 17:00:54
	System	20 Oct 2020 17:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Oct 2020 17:13:37
User entered 'Day 44'	System	19 Oct 2020 17:13:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b604fa7e-ee50-4292-b6e1-4bc41791ccab'	System	22 Oct 2020 01:50:36
User entered 'No interference with activity (1)'	System	22 Oct 2020 01:50:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b604fa7e-ee50-4292-b6e1-4bc41791ccab' User entered '21 Oct 2020 20:50'	System	22 Oct 2020 01:50:36
	System	22 Oct 2020 01:50:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:37

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:37



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Oct 2020 17:00:54
User entered 'Day 45'	System	20 Oct 2020 17:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fec15eba-4c88-4ee9-bf54-9237c4378438'	System	23 Oct 2020 12:19:17
User entered 'No interference with activity (1)'	System	23 Oct 2020 12:19:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:00:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'fec15eba-4c88-4ee9-bf54-9237c4378438'	System	23 Oct 2020 12:19:17
User entered '22 Oct 2020 12:00'	System	23 Oct 2020 12:19:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Oct 2020 01:50:36
User entered 'Day 46'	System	22 Oct 2020 01:50:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a06baad4-9fe2-41a4-96ac-179598ed2ae4'	System	23 Oct 2020 17:29:55
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:29:55

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a06baad4-9fe2-41a4-96ac-179598ed2ae4' User entered '23 Oct 2020 12:29'	System	23 Oct 2020 17:29:55
	System	23 Oct 2020 17:29:55



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:50:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:50:36

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 12:19:17
User entered 'Day 47'	System	23 Oct 2020 12:19:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:11:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'be1cf917-1e94-4da4-bd75-992216f6e13e'	System	24 Oct 2020 17:11:16
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:11:16

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:11:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'be1cf917-1e94-4da4-bd75-992216f6e13e' User entered '24 Oct 2020 12:11'	System	24 Oct 2020 17:11:16
	System	24 Oct 2020 17:11:16

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:19:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:19:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 17:29:55
User entered 'Day 48'	System	23 Oct 2020 17:29:55



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8287f669-e43b-4303-ab0a-92a2bf190536'	System	26 Oct 2020 10:53:03
User entered 'No interference with activity (1)'	System	26 Oct 2020 10:53:03

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:52:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8287f669-e43b-4303-ab0a-92a2bf190536' User entered '26 Oct 2020 05:52'	System	26 Oct 2020 10:53:03
	System	26 Oct 2020 10:53:03

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:29:55

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:29:55

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Oct 2020 17:11:16
User entered 'Day 49'	System	24 Oct 2020 17:11:16

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfb725fd-649d-4c4d-aaa3-ddf0e6593921'	System	26 Oct 2020 17:13:28
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:13:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfb725fd-649d-4c4d-aaa3-ddf0e6593921' User entered '26 Oct 2020 12:13'	System	26 Oct 2020 17:13:28
	System	26 Oct 2020 17:13:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:11:16



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:11:16

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 10:53:03
User entered 'Day 50'	System	26 Oct 2020 10:53:03

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c61f283-e3dd-4338-b2fb-a8401319655c'	System	27 Oct 2020 17:01:17
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:01:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c61f283-e3dd-4338-b2fb-a8401319655c' User entered '27 Oct 2020 12:00'	System	27 Oct 2020 17:01:17
	System	27 Oct 2020 17:01:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 10:53:03

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 10:53:03

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 17:13:28
User entered 'Day 51'	System	26 Oct 2020 17:13:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '341bdc6d-41ed-4efc-8734-9a0bf372370c'	System	28 Oct 2020 17:06:28
User entered 'No interference with activity (1)'	System	28 Oct 2020 17:06:28



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '341bdc6d-41ed-4efc-8734-9a0bf372370c' User entered '28 Oct 2020 12:04'	System	28 Oct 2020 17:06:28
	System	28 Oct 2020 17:06:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:13:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:13:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Oct 2020 17:01:17
User entered 'Day 52'	System	27 Oct 2020 17:01:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53c19ee3-9f2a-405e-bda6-5dc8ce45ab75'	System	29 Oct 2020 17:28:50
User entered 'No interference with activity (1)'	System	29 Oct 2020 17:28:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '53c19ee3-9f2a-405e-bda6-5dc8ce45ab75' User entered '29 Oct 2020 12:28'	System	29 Oct 2020 17:28:50
	System	29 Oct 2020 17:28:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:01:17

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:01:17



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Oct 2020 17:06:28
User entered 'Day 53'	System	28 Oct 2020 17:06:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c9a82af0-daf7-44ac-ac74-5b038fc6813a'	System	30 Oct 2020 19:03:47
User entered 'No interference with activity (1)'	System	30 Oct 2020 19:03:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c9a82af0-daf7-44ac-ac74-5b038fc6813a' User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:03:47
	System	30 Oct 2020 19:03:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:06:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:06:28

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Oct 2020 17:28:50
User entered 'Day 54'	System	29 Oct 2020 17:28:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1fb6d1b6-2a3a-4a02-99a4-6b776c77d18e'	System	31 Oct 2020 20:35:46
User entered 'No interference with activity (1)'	System	31 Oct 2020 20:35:46

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1fb6d1b6-2a3a-4a02-99a4-6b776c77d18e' User entered '31 Oct 2020 15:35'	System	31 Oct 2020 20:35:46
	System	31 Oct 2020 20:35:46



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:28:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:28:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Oct 2020 19:03:47
User entered 'Day 55'	System	30 Oct 2020 19:03:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0b9d1fc9-0e97-4653-9fe5-a2ff97e8aa8f' User entered 'No interference with activity (1)'	System	01 Nov 2020 17:32:20
	System	01 Nov 2020 17:32:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0b9d1fc9-0e97-4653-9fe5-a2ff97e8aa8f' User entered '01 Nov 2020 12:32'	System	01 Nov 2020 17:32:20
	System	01 Nov 2020 17:32:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:03:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:03:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Oct 2020 20:35:46
User entered 'Day 56'	System	31 Oct 2020 20:35:46



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e651ab85-19f8-45de-b9f0-c3dce9450180'	System	02 Nov 2020 19:20:50
User entered 'No interference with activity (1)'	System	02 Nov 2020 19:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e651ab85-19f8-45de-b9f0-c3dce9450180'	System	02 Nov 2020 19:20:50
User entered '02 Nov 2020 14:20'	System	02 Nov 2020 19:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 20:35:46

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 20:35:46

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Nov 2020 17:32:20
User entered 'Day 57'	System	01 Nov 2020 17:32:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef5662a5-957f-4c24-afe5-2ed2a3e4fb85'	System	03 Nov 2020 18:08:19
User entered 'No interference with activity (1)'	System	03 Nov 2020 18:08:19

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef5662a5-957f-4c24-afe5-2ed2a3e4fb85'	System	03 Nov 2020 18:08:19
User entered '03 Nov 2020 12:08'	System	03 Nov 2020 18:08:19

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:32:20



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:32:20

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Nov 2020 19:20:50
User entered 'Day 58'	System	02 Nov 2020 19:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a30e4385-5478-4624-b5ef-4b769a7a99f2'	System	04 Nov 2020 18:00:51
User entered 'No interference with activity (1)'	System	04 Nov 2020 18:00:51

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a30e4385-5478-4624-b5ef-4b769a7a99f2'	System	04 Nov 2020 18:00:51
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:51

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 19:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 19:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Nov 2020 18:08:19
User entered 'Day 59'	System	03 Nov 2020 18:08:19

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7407fe35-579c-41e2-8a8c-e0b5c90c3cd6'	System	05 Nov 2020 18:24:05
User entered 'No interference with activity (1)'	System	05 Nov 2020 18:24:05



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:23:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7407fe35-579c-41e2-8a8c-e0b5c90c3cd6' User entered '05 Nov 2020 12:23'	System	05 Nov 2020 18:24:05
	System	05 Nov 2020 18:24:05

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:08:19

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:08:19

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Nov 2020 18:00:51
User entered 'Day 60'	System	04 Nov 2020 18:00:51

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3deda75e-e988-4b1d-8529-068455a41075'	System	06 Nov 2020 18:25:38
User entered 'No interference with activity (1)'	System	06 Nov 2020 18:25:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3deda75e-e988-4b1d-8529-068455a41075' User entered '06 Nov 2020 12:25'	System	06 Nov 2020 18:25:38
	System	06 Nov 2020 18:25:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:51

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:51



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Nov 2020 18:24:05
User entered 'Day 61'	System	05 Nov 2020 18:24:05

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ce6205ef-3385-4022-8634-69bf33830223'	System	07 Nov 2020 18:06:48
User entered 'No interference with activity (1)'	System	07 Nov 2020 18:06:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ce6205ef-3385-4022-8634-69bf33830223'	System	07 Nov 2020 18:06:48
User entered '07 Nov 2020 12:06'	System	07 Nov 2020 18:06:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:24:05

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:24:05

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Nov 2020 18:25:38
User entered 'Day 62'	System	06 Nov 2020 18:25:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c9e91f9-1f17-406a-8ca1-e1c0747eaaf1'	System	09 Nov 2020 12:16:54
User entered 'No interference with activity (1)'	System	09 Nov 2020 12:16:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9c9e91f9-1f17-406a-8ca1-e1c0747eaaf1' User entered '09 Nov 2020 06:16'	System	09 Nov 2020 12:16:54
	System	09 Nov 2020 12:16:54



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 18:25:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 18:25:38

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Nov 2020 18:06:48
User entered 'Day 63'	System	07 Nov 2020 18:06:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '583d9bf6-fe0c-4470-a53f-33dcb56286d5'	System	09 Nov 2020 18:21:29
User entered 'No interference with activity (1)'	System	09 Nov 2020 18:21:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '583d9bf6-fe0c-4470-a53f-33dcb56286d5' User entered '09 Nov 2020 12:21'	System	09 Nov 2020 18:21:29
	System	09 Nov 2020 18:21:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:06:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:06:48

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 12:16:54
User entered 'Day 64'	System	09 Nov 2020 12:16:54



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '38a01b84-f689-4683-b4c4-4d7bb2d98141'	System	10 Nov 2020 18:03:39
User entered 'No interference with activity (1)'	System	10 Nov 2020 18:03:39

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '38a01b84-f689-4683-b4c4-4d7bb2d98141' User entered '10 Nov 2020 12:03'	System	10 Nov 2020 18:03:39
	System	10 Nov 2020 18:03:39

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 12:16:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 12:16:54

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 18:21:29
User entered 'Day 65'	System	09 Nov 2020 18:21:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0beefe45-4a39-4a7c-9387-d2a67804fc5d'	System	11 Nov 2020 18:00:47
User entered 'No interference with activity (1)'	System	11 Nov 2020 18:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0beefe45-4a39-4a7c-9387-d2a67804fc5d' User entered '11 Nov 2020 12:00'	System	11 Nov 2020 18:00:47
	System	11 Nov 2020 18:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:21:29



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:21:29

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Nov 2020 18:03:39
User entered 'Day 66'	System	10 Nov 2020 18:03:39

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62bc7dda-2ae4-40d9-857a-fa3c36b5d654'	System	12 Nov 2020 18:00:43
User entered 'No interference with activity (1)'	System	12 Nov 2020 18:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62bc7dda-2ae4-40d9-857a-fa3c36b5d654'	System	12 Nov 2020 18:00:43
User entered '12 Nov 2020 12:00'	System	12 Nov 2020 18:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:03:39

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:03:39

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Nov 2020 18:00:47
User entered 'Day 67'	System	11 Nov 2020 18:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50a68b4a-b767-423d-9275-7386c7d8d6c3'	System	13 Nov 2020 18:38:24
User entered 'No interference with activity (1)'	System	13 Nov 2020 18:38:24



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '50a68b4a-b767-423d-9275-7386c7d8d6c3'	System	13 Nov 2020 18:38:24
User entered '13 Nov 2020 12:38'	System	13 Nov 2020 18:38:24

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 18:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 18:00:47

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Nov 2020 18:00:43
User entered 'Day 68'	System	12 Nov 2020 18:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0544d0c7-fe4c-41f1-9325-ebe677ad3982'	System	15 Nov 2020 09:46:59
User entered 'No interference with activity (1)'	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0544d0c7-fe4c-41f1-9325-ebe677ad3982'	System	15 Nov 2020 09:46:59
User entered '14 Nov 2020 12:33'	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:00:43

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:00:43



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Nov 2020 18:38:24
User entered 'Day 69'	System	13 Nov 2020 18:38:24

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2959de-7b14-4d61-b752-78e27003cd44'	System	15 Nov 2020 18:00:41
User entered 'No interference with activity (1)'	System	15 Nov 2020 18:00:41

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f2959de-7b14-4d61-b752-78e27003cd44'	System	15 Nov 2020 18:00:41
User entered '15 Nov 2020 12:00'	System	15 Nov 2020 18:00:41

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 18:38:24

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 18:38:24

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 09:46:59
User entered 'Day 70'	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '233ce9ba-bcd1-4698-9d19-3b0fc6f6ef93'	System	16 Nov 2020 18:00:44
User entered 'No interference with activity (1)'	System	16 Nov 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '233ce9ba-bcd1-4698-9d19-3b0fc6f6ef93'	System	16 Nov 2020 18:00:44
User entered '16 Nov 2020 12:00'	System	16 Nov 2020 18:00:44



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 18:00:41
User entered 'Day 71'	System	15 Nov 2020 18:00:41

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9815cdb6-5513-4fd4-9bbd-dd42362cad94'	System	17 Nov 2020 23:33:40
User entered 'No interference with activity (1)'	System	17 Nov 2020 23:33:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9815cdb6-5513-4fd4-9bbd-dd42362cad94' User entered '17 Nov 2020 17:33'	System	17 Nov 2020 23:33:40
	System	17 Nov 2020 23:33:40

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:00:41

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(71)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:00:41

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Nov 2020 18:00:44
User entered 'Day 72'	System	16 Nov 2020 18:00:44



US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:28:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '89ed4b36-cdc9-42e0-9bfa-c0a54f889a07' User entered 'None (0)'	System	18 Nov 2020 22:28:09
	System	18 Nov 2020 22:28:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:28:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '89ed4b36-cdc9-42e0-9bfa-c0a54f889a07'	System	18 Nov 2020 22:28:09
User entered '18 Nov 2020 16:28'	System	18 Nov 2020 22:28:09

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Sep 2020 19:23:06
User entered 'Day 8'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '725a2c2d-6d90-43cf-9de0-55c2c45389fe' User entered 'No (N)'	System	15 Sep 2020 17:17:30
	System	15 Sep 2020 17:17:30

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-15T12:17:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '725a2c2d-6d90-43cf-9de0-55c2c45389fe' User entered '15 Sep 2020 12:17'	System	15 Sep 2020 17:17:30
	System	15 Sep 2020 17:17:30

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:23:06



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:23:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Sep 2020 17:13:17
User entered 'Day 9'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:00:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2fc5ee87-0ec3-4f84-b05f-d4c1b9d09ab8'	System	16 Sep 2020 17:01:29
User entered 'No (N)'	System	16 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-16T12:01:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2fc5ee87-0ec3-4f84-b05f-d4c1b9d09ab8'	System	16 Sep 2020 17:01:29
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 17:01:29

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:13:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Sep 2020 17:17:08
User entered 'Day 10'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:01:04', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '35a289e7-6c07-47b1-8af0-a5fab8d61a10' User entered 'No (N)'	System	17 Sep 2020 17:01:56
	System	17 Sep 2020 17:01:56



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-17T12:01:08', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '35a289e7-6c07-47b1-8af0-a5fab8d61a10' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:01:56
	System	17 Sep 2020 17:01:56

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:17:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Sep 2020 17:00:31
User entered 'Day 11'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7cbb0e1-b99e-4510-b8b5-bc979504633d' User entered 'No (N)'	System	19 Sep 2020 11:10:35
	System	19 Sep 2020 11:10:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T06:10:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7cbb0e1-b99e-4510-b8b5-bc979504633d' User entered '19 Sep 2020 06:10'	System	19 Sep 2020 11:10:35
	System	19 Sep 2020 11:10:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:31



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	17 Sep 2020 17:00:48
User entered 'Day 12'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '754daf2f-6bce-411a-8a84-d0657509525e' User entered 'No (N)'	System	19 Sep 2020 17:00:44
	System	19 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-19T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '754daf2f-6bce-411a-8a84-d0657509525e' User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:00:44
	System	19 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:00:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 11:09:57
User entered 'Day 13'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b39e0d7-8d31-4604-8485-cba250360a90'	System	20 Sep 2020 17:00:49
User entered 'No (N)'	System	20 Sep 2020 17:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-20T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5b39e0d7-8d31-4604-8485-cba250360a90'	System	20 Sep 2020 17:00:49
User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:49



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 11:09:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Sep 2020 17:00:21
User entered 'Day 14'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4823250b-efde-4d9f-b14e-dbd8fd106ae0' User entered 'No (N)'	System	21 Sep 2020 17:03:52
	System	21 Sep 2020 17:03:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-21T12:00:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4823250b-efde-4d9f-b14e-dbd8fd106ae0' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:52
	System	21 Sep 2020 17:03:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Sep 2020 17:00:16
User entered 'Day 15'	System	20 Sep 2020 17:00:16



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '48d3f52d-d666-4809-b0be-56b8ae5e95c2'	System	22 Sep 2020 17:09:43
User entered 'No (N)'	System	22 Sep 2020 17:09:43

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-22T12:09:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '48d3f52d-d666-4809-b0be-56b8ae5e95c2'	System	22 Sep 2020 17:09:43
User entered '22 Sep 2020 12:09'	System	22 Sep 2020 17:09:43

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 17:00:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	21 Sep 2020 17:02:21
User entered 'Day 16'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c10aa979-5463-4e15-ac6a-86599cb598b0' User entered 'No (N)'	System	24 Sep 2020 10:25:41
	System	24 Sep 2020 10:25:41

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T05:25:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c10aa979-5463-4e15-ac6a-86599cb598b0' User entered '24 Sep 2020 05:25'	System	24 Sep 2020 10:25:41
	System	24 Sep 2020 10:25:41

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:02:21



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:02:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Sep 2020 17:09:28
User entered 'Day 17'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62c28073-63ec-4263-bba4-63f8b1b581a5' User entered 'No (N)'	System	24 Sep 2020 17:15:28
	System	24 Sep 2020 17:15:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-24T12:15:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '62c28073-63ec-4263-bba4-63f8b1b581a5' User entered '24 Sep 2020 12:15'	System	24 Sep 2020 17:15:28
	System	24 Sep 2020 17:15:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:09:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 10:25:17
User entered 'Day 18'	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:01:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ca2b375c-5f2a-4b68-b0f6-01871d5f3af0' User entered 'No (N)'	System	25 Sep 2020 17:02:46
	System	25 Sep 2020 17:02:46



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-25T12:01:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ca2b375c-5f2a-4b68-b0f6-01871d5f3af0' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:46
	System	25 Sep 2020 17:02:46

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:25:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Sep 2020 17:15:06
User entered 'Day 19'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '29cde1c8-0e05-493b-93d4-d635a355d13f' User entered 'No (N)'	System	26 Sep 2020 17:01:25
	System	26 Sep 2020 17:01:25

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-26T12:00:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '29cde1c8-0e05-493b-93d4-d635a355d13f' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 17:01:25
	System	26 Sep 2020 17:01:25

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:15:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:15:06



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	25 Sep 2020 17:01:28
User entered 'Day 20'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ad186e2b-14bc-4b77-8d77-6686ea99e1e2' User entered 'No (N)'	System	28 Sep 2020 11:02:59
	System	28 Sep 2020 11:02:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T06:02:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ad186e2b-14bc-4b77-8d77-6686ea99e1e2' User entered '28 Sep 2020 06:02'	System	28 Sep 2020 11:02:59
	System	28 Sep 2020 11:02:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:01:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Sep 2020 17:00:44
User entered 'Day 21'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '68b0f3a9-8908-4079-a7e0-339493c7fc0c' User entered 'No (N)'	System	28 Sep 2020 17:04:09
	System	28 Sep 2020 17:04:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-28T12:03:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '68b0f3a9-8908-4079-a7e0-339493c7fc0c' User entered '28 Sep 2020 12:03'	System	28 Sep 2020 17:04:09
	System	28 Sep 2020 17:04:09



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:00:44

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 11:02:23
User entered 'Day 22'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '297f7945-1562-4511-b96e-50e128531dd4'	System	29 Sep 2020 17:06:42
User entered 'No (N)'	System	29 Sep 2020 17:06:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-29T12:06:40', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '297f7945-1562-4511-b96e-50e128531dd4'	System	29 Sep 2020 17:06:42
User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:06:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:02:23

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Sep 2020 17:03:51
User entered 'Day 23'	System	28 Sep 2020 17:03:51



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8489f388-04f5-4839-b10e-7ee76f1d25ec' User entered 'No (N)'	System	30 Sep 2020 17:20:50
	System	30 Sep 2020 17:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-09-30T12:20:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8489f388-04f5-4839-b10e-7ee76f1d25ec'	System	30 Sep 2020 17:20:50
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:20:50

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:03:51

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Sep 2020 17:06:20
User entered 'Day 24'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:40:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '144a142d-5571-49a2-b6ba-696a68d8f7b8' User entered 'No (N)'	System	01 Oct 2020 19:40:17
	System	01 Oct 2020 19:40:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-01T14:40:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '144a142d-5571-49a2-b6ba-696a68d8f7b8' User entered '01 Oct 2020 14:40'	System	01 Oct 2020 19:40:17
	System	01 Oct 2020 19:40:17

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:06:20



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:06:20

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Sep 2020 17:20:19
User entered 'Day 25'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:04:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0d8b26db-5598-4d47-87c7-d19d76af6a59'	System	02 Oct 2020 17:05:47
User entered 'No (N)'	System	02 Oct 2020 17:05:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-02T12:04:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0d8b26db-5598-4d47-87c7-d19d76af6a59' User entered '02 Oct 2020 12:04'	System	02 Oct 2020 17:05:47
	System	02 Oct 2020 17:05:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:20:19

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Oct 2020 19:39:56
User entered 'Day 26'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ecce171d-341c-438b-b41e-fcec5414c0bd' User entered 'No (N)'	System	04 Oct 2020 10:59:46
	System	04 Oct 2020 10:59:46



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T05:59:44', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ecce171d-341c-438b-b41e-fcec5414c0bd' User entered '04 Oct 2020 05:59'	System	04 Oct 2020 10:59:46
	System	04 Oct 2020 10:59:46

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:39:56

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Oct 2020 17:03:06
User entered 'Day 27'	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5394ef09-8965-4c08-8247-fe4716b96df4'	System	04 Oct 2020 17:00:52
User entered 'No (N)'	System	04 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-04T12:00:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5394ef09-8965-4c08-8247-fe4716b96df4' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:52
	System	04 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:03:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:03:06



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 10:59:20
User entered 'Day 28'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:13:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3044e566-a91d-491b-8896-8a386df8cd66'	System	05 Oct 2020 17:13:11
User entered 'No (N)'	System	05 Oct 2020 17:13:11

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-05T12:13:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3044e566-a91d-491b-8896-8a386df8cd66' User entered '05 Oct 2020 12:13'	System	05 Oct 2020 17:13:11
	System	05 Oct 2020 17:13:11

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 10:59:20

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Oct 2020 17:00:21
User entered 'Day 29'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:44:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4a27c30b-857d-4efd-bb10-7753c3791aad' User entered 'No (N)'	System	06 Oct 2020 17:44:21
	System	06 Oct 2020 17:44:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-06T12:44:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4a27c30b-857d-4efd-bb10-7753c3791aad' User entered '06 Oct 2020 12:44'	System	06 Oct 2020 17:44:21
	System	06 Oct 2020 17:44:21



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:00:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Oct 2020 17:12:48
User entered 'Day 30'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8906c453-77ae-4b54-a57e-0bb280c2dbcd' User entered 'No (N)'	System	07 Oct 2020 17:36:57
	System	07 Oct 2020 17:36:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-07T12:36:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8906c453-77ae-4b54-a57e-0bb280c2dbcd' User entered '07 Oct 2020 12:36'	System	07 Oct 2020 17:36:57
	System	07 Oct 2020 17:36:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:12:48

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Oct 2020 17:43:54
User entered 'Day 31'	System	06 Oct 2020 17:43:54



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd9acf198-8451-428b-8fce-459b39481b2c'	System	08 Oct 2020 18:00:53
User entered 'No (N)'	System	08 Oct 2020 18:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-08T13:00:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd9acf198-8451-428b-8fce-459b39481b2c' User entered '08 Oct 2020 13:00'	System	08 Oct 2020 18:00:53
	System	08 Oct 2020 18:00:53

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:43:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Oct 2020 17:36:35
User entered 'Day 32'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:00:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7256c21a-aed1-4cf9-9298-83ee98cda2ef' User entered 'No (N)'	System	09 Oct 2020 17:01:54
	System	09 Oct 2020 17:01:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-09T12:01:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7256c21a-aed1-4cf9-9298-83ee98cda2ef' User entered '09 Oct 2020 12:01'	System	09 Oct 2020 17:01:54
	System	09 Oct 2020 17:01:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:36:35



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:36:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	08 Oct 2020 18:00:32
User entered 'Day 33'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6b101785-2e88-4246-abbe-eb35594b59a9'	System	10 Oct 2020 17:25:08
User entered 'No (N)'	System	10 Oct 2020 17:25:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-10T12:24:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6b101785-2e88-4246-abbe-eb35594b59a9' User entered '10 Oct 2020 12:24'	System	10 Oct 2020 17:25:08
	System	10 Oct 2020 17:25:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:00:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Oct 2020 17:00:26
User entered 'Day 34'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:47:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9511a103-4b03-444d-8bc5-7bcc2b77c04f' User entered 'No (N)'	System	11 Oct 2020 17:47:16
	System	11 Oct 2020 17:47:16



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:47:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9511a103-4b03-444d-8bc5-7bcc2b77c04f' User entered '11 Oct 2020 12:47'	System	11 Oct 2020 17:47:16
	System	11 Oct 2020 17:47:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Oct 2020 17:24:31
User entered 'Day 35'	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:54', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3ad8d9b4-15f4-4418-979d-f7b8ce756714' User entered 'No (N)'	System	12 Oct 2020 17:33:03
	System	12 Oct 2020 17:33:03

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-12T12:32:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3ad8d9b4-15f4-4418-979d-f7b8ce756714'	System	12 Oct 2020 17:33:03
User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:33:03

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:24:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:24:31



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Oct 2020 17:46:32
User entered 'Day 36'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:08:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '60582adb-e6fc-4488-89d0-38fc99e90a79'	System	13 Oct 2020 17:08:07
User entered 'No (N)'	System	13 Oct 2020 17:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-13T12:08:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '60582adb-e6fc-4488-89d0-38fc99e90a79' User entered '13 Oct 2020 12:08'	System	13 Oct 2020 17:08:07
	System	13 Oct 2020 17:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 17:46:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Oct 2020 17:32:41
User entered 'Day 37'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4262203f-732c-4258-aa09-7a623f175055'	System	14 Oct 2020 17:01:58
User entered 'No (N)'	System	14 Oct 2020 17:01:58

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-14T12:01:23', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4262203f-732c-4258-aa09-7a623f175055'	System	14 Oct 2020 17:01:58
User entered '14 Oct 2020 12:01'	System	14 Oct 2020 17:01:58



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 17:32:41

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Oct 2020 17:07:45
User entered 'Day 38'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ea098998-1ea7-4919-8351-861cab060d97'	System	15 Oct 2020 17:02:10
User entered 'No (N)'	System	15 Oct 2020 17:02:10

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-15T12:01:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ea098998-1ea7-4919-8351-861cab060d97' User entered '15 Oct 2020 12:01'	System	15 Oct 2020 17:02:10
	System	15 Oct 2020 17:02:10

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:07:45

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	14 Oct 2020 17:01:38
User entered 'Day 39'	System	14 Oct 2020 17:01:38



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:30', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2c3fdd52-0e61-46a8-91ba-0eef94a7edb0'	System	16 Oct 2020 17:01:55
User entered 'No (N)'	System	16 Oct 2020 17:01:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-16T12:01:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2c3fdd52-0e61-46a8-91ba-0eef94a7edb0' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 17:01:55
	System	16 Oct 2020 17:01:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:01:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Oct 2020 17:01:16
User entered 'Day 40'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:16:01', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f500645d-9729-41d7-8fab-3f5c0a024aec'	System	18 Oct 2020 14:16:06
User entered 'No (N)'	System	18 Oct 2020 14:16:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:16:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f500645d-9729-41d7-8fab-3f5c0a024aec'	System	18 Oct 2020 14:16:06
User entered '18 Oct 2020 09:16'	System	18 Oct 2020 14:16:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:01:16



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:01:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Oct 2020 17:01:24
User entered 'Day 41'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:38', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '21717512-8573-462f-8797-bcdcfca10cff'	System	18 Oct 2020 17:00:49
User entered 'No (N)'	System	18 Oct 2020 17:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T12:00:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '21717512-8573-462f-8797-bcdcfca10cff' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 17:00:49
	System	18 Oct 2020 17:00:49

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:01:24

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 14:15:40
User entered 'Day 42'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8074cd1b-8efc-4e16-9314-dd8c42905b52'	System	19 Oct 2020 17:13:38
User entered 'No (N)'	System	19 Oct 2020 17:13:38



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-19T12:13:37', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8074cd1b-8efc-4e16-9314-dd8c42905b52'	System	19 Oct 2020 17:13:38
User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 14:15:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	18 Oct 2020 17:00:24
User entered 'Day 43'	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'edcb157a-6b3d-4492-979f-7bb2aa31072e' User entered 'No (N)'	System	20 Oct 2020 17:01:13
	System	20 Oct 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-20T12:00:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'edcb157a-6b3d-4492-979f-7bb2aa31072e' User entered '20 Oct 2020 12:00'	System	20 Oct 2020 17:01:13
	System	20 Oct 2020 17:01:13

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:24

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:24



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	19 Oct 2020 17:13:13
User entered 'Day 44'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1dec9171-41f5-4cd7-aba3-e74a3180fb4a'	System	22 Oct 2020 01:50:47
User entered 'No (N)'	System	22 Oct 2020 01:50:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-21T20:50:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1dec9171-41f5-4cd7-aba3-e74a3180fb4a' User entered '21 Oct 2020 20:50'	System	22 Oct 2020 01:50:47
	System	22 Oct 2020 01:50:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:13

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	20 Oct 2020 17:00:36
User entered 'Day 45'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:01:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '759b18d7-5269-4916-bf30-8a3e31a41833'	System	23 Oct 2020 12:19:18
User entered 'No (N)'	System	23 Oct 2020 12:19:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-22T12:01:22', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '759b18d7-5269-4916-bf30-8a3e31a41833' User entered '22 Oct 2020 12:01'	System	23 Oct 2020 12:19:18
	System	23 Oct 2020 12:19:18



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:00:36

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	22 Oct 2020 01:50:09
User entered 'Day 46'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '58c6bfc6-c724-4855-b577-7af07af12911'	System	23 Oct 2020 17:29:55
User entered 'No (N)'	System	23 Oct 2020 17:29:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-23T12:29:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '58c6bfc6-c724-4855-b577-7af07af12911'	System	23 Oct 2020 17:29:55
User entered '23 Oct 2020 12:29'	System	23 Oct 2020 17:29:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:50:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 12:19:14
User entered 'Day 47'	System	23 Oct 2020 12:19:14



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:11:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '132b437c-1b1f-4256-afb9-a902baf525a9' User entered 'No (N)'	System	24 Oct 2020 17:11:21
	System	24 Oct 2020 17:11:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-24T12:11:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '132b437c-1b1f-4256-afb9-a902baf525a9' User entered '24 Oct 2020 12:11'	System	24 Oct 2020 17:11:21
	System	24 Oct 2020 17:11:21

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:19:14

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	23 Oct 2020 17:29:16
User entered 'Day 48'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:53:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '83ccf48a-6bbb-4b8a-a282-48bc7abf1c5c' User entered 'No (N)'	System	26 Oct 2020 10:53:08
	System	26 Oct 2020 10:53:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T05:53:06', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '83ccf48a-6bbb-4b8a-a282-48bc7abf1c5c' User entered '26 Oct 2020 05:53'	System	26 Oct 2020 10:53:08
	System	26 Oct 2020 10:53:08

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:29:16



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:29:16

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	24 Oct 2020 17:10:55
User entered 'Day 49'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e4c440e-e3f1-4c7b-ab28-cd9b07fbaa0c' User entered 'No (N)'	System	26 Oct 2020 17:13:38
	System	26 Oct 2020 17:13:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-26T12:13:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0e4c440e-e3f1-4c7b-ab28-cd9b07fbaa0c' User entered '26 Oct 2020 12:13'	System	26 Oct 2020 17:13:38
	System	26 Oct 2020 17:13:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:10:55

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 10:52:47
User entered 'Day 50'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '763d18ef-e0f1-4128-8525-56db0518621f' User entered 'No (N)'	System	27 Oct 2020 17:01:26
	System	27 Oct 2020 17:01:26



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-27T12:00:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '763d18ef-e0f1-4128-8525-56db0518621f' User entered '27 Oct 2020 12:00'	System	27 Oct 2020 17:01:26
	System	27 Oct 2020 17:01:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 10:52:47

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	26 Oct 2020 17:12:58
User entered 'Day 51'	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'edfc2607-2994-4e20-9a4c-7cf58ef5a725'	System	28 Oct 2020 17:06:35
User entered 'No (N)'	System	28 Oct 2020 17:06:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-28T12:04:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'edfc2607-2994-4e20-9a4c-7cf58ef5a725'	System	28 Oct 2020 17:06:35
User entered '28 Oct 2020 12:04'	System	28 Oct 2020 17:06:35

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:12:58

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:12:58



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	27 Oct 2020 17:00:52
User entered 'Day 52'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c5ef864b-4413-45f8-a944-51c89de2d98f' User entered 'No (N)'	System	29 Oct 2020 17:28:59
	System	29 Oct 2020 17:28:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-29T12:28:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c5ef864b-4413-45f8-a944-51c89de2d98f' User entered '29 Oct 2020 12:28'	System	29 Oct 2020 17:28:59
	System	29 Oct 2020 17:28:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	28 Oct 2020 17:06:15
User entered 'Day 53'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '13ec25af-739d-41e5-b281-ae1917930f4b' User entered 'No (N)'	System	30 Oct 2020 19:03:56
	System	30 Oct 2020 19:03:56

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-30T14:03:53', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '13ec25af-739d-41e5-b281-ae1917930f4b' User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:03:56
	System	30 Oct 2020 19:03:56



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:06:15

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	29 Oct 2020 17:28:40
User entered 'Day 54'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '902508b2-5d96-4270-8be8-8461d4dd6c3f' User entered 'No (N)'	System	31 Oct 2020 20:35:52
	System	31 Oct 2020 20:35:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-31T15:35:50', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '902508b2-5d96-4270-8be8-8461d4dd6c3f' User entered '31 Oct 2020 15:35'	System	31 Oct 2020 20:35:52
	System	31 Oct 2020 20:35:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:28:40

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	30 Oct 2020 19:03:28
User entered 'Day 55'	System	30 Oct 2020 19:03:28



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e97374c2-3262-4a4f-894f-e59ad3c9cea3'	System	01 Nov 2020 17:32:27
User entered 'No (N)'	System	01 Nov 2020 17:32:27

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-01T12:32:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e97374c2-3262-4a4f-894f-e59ad3c9cea3'	System	01 Nov 2020 17:32:27
User entered '01 Nov 2020 12:32'	System	01 Nov 2020 17:32:27

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:03:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	31 Oct 2020 20:35:31
User entered 'Day 56'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:52', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a56cf943-2e28-4e0d-82e9-cef1f5d14bd3'	System	02 Nov 2020 19:20:59
User entered 'No (N)'	System	02 Nov 2020 19:20:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-02T14:20:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'a56cf943-2e28-4e0d-82e9-cef1f5d14bd3' User entered '02 Nov 2020 14:20'	System	02 Nov 2020 19:20:59
	System	02 Nov 2020 19:20:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 20:35:31



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 20:35:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	01 Nov 2020 17:32:10
User entered 'Day 57'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e253aed3-350d-464d-8bcb-22199085523b' User entered 'No (N)'	System	03 Nov 2020 18:08:31
	System	03 Nov 2020 18:08:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-03T12:08:26', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e253aed3-350d-464d-8bcb-22199085523b' User entered '03 Nov 2020 12:08'	System	03 Nov 2020 18:08:31
	System	03 Nov 2020 18:08:31

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:32:10

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	02 Nov 2020 19:20:32
User entered 'Day 58'	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:00:49', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '61be6d10-9238-4755-9909-9d50009ce45c' User entered 'No (N)'	System	04 Nov 2020 18:01:12
	System	04 Nov 2020 18:01:12



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-04T12:01:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '61be6d10-9238-4755-9909-9d50009ce45c' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:01:12
	System	04 Nov 2020 18:01:12

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 19:20:32

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	03 Nov 2020 18:08:07
User entered 'Day 59'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:24:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1f15bded-2ac2-4455-b614-7f011de8c76a' User entered 'No (N)'	System	05 Nov 2020 18:24:06
	System	05 Nov 2020 18:24:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-05T12:24:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1f15bded-2ac2-4455-b614-7f011de8c76a' User entered '05 Nov 2020 12:24'	System	05 Nov 2020 18:24:06
	System	05 Nov 2020 18:24:06

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:08:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(59)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:08:07



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	04 Nov 2020 18:00:42
User entered 'Day 60'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '88609291-1192-4c2c-baf3-18191e5a9021' User entered 'No (N)'	System	06 Nov 2020 18:25:42
	System	06 Nov 2020 18:25:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-06T12:25:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '88609291-1192-4c2c-baf3-18191e5a9021' User entered '06 Nov 2020 12:25'	System	06 Nov 2020 18:25:42
	System	06 Nov 2020 18:25:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(60)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:42

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	05 Nov 2020 18:23:43
User entered 'Day 61'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '47cab3b1-c68b-40d8-b4c4-f79546d2a31b' User entered 'No (N)'	System	07 Nov 2020 18:06:53
	System	07 Nov 2020 18:06:53

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-07T12:06:51', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '47cab3b1-c68b-40d8-b4c4-f79546d2a31b' User entered '07 Nov 2020 12:06'	System	07 Nov 2020 18:06:53
	System	07 Nov 2020 18:06:53



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(61)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:23:43

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	06 Nov 2020 18:25:18
User entered 'Day 62'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:16:56', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7d2f6133-8e10-4a55-8e8c-2b05ded9421d' User entered 'No (N)'	System	09 Nov 2020 12:17:02
	System	09 Nov 2020 12:17:02

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T06:17:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '7d2f6133-8e10-4a55-8e8c-2b05ded9421d' User entered '09 Nov 2020 06:17'	System	09 Nov 2020 12:17:02
	System	09 Nov 2020 12:17:02

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(62)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 18:25:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	07 Nov 2020 18:06:26
User entered 'Day 63'	System	07 Nov 2020 18:06:26



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b6be5387-f07b-4e33-94a6-546cb0ee9acc' User entered 'No (N)'	System	09 Nov 2020 18:21:38
	System	09 Nov 2020 18:21:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-09T12:21:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b6be5387-f07b-4e33-94a6-546cb0ee9acc' User entered '09 Nov 2020 12:21'	System	09 Nov 2020 18:21:38
	System	09 Nov 2020 18:21:38

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(63)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:06:26

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 12:16:36
User entered 'Day 64'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6360320c-fffe-429f-84c5-c14c6634f75a'	System	10 Nov 2020 18:03:46
User entered 'No (N)'	System	10 Nov 2020 18:03:46

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-10T12:03:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6360320c-fffe-429f-84c5-c14c6634f75a' User entered '10 Nov 2020 12:03'	System	10 Nov 2020 18:03:46
	System	10 Nov 2020 18:03:46

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 12:16:36



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(64)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 12:16:36

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	09 Nov 2020 18:21:09
User entered 'Day 65'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1b902c3a-6aa8-4395-a29a-6b3f94ccf2bc' User entered 'No (N)'	System	11 Nov 2020 18:00:54
	System	11 Nov 2020 18:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-11T12:00:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '1b902c3a-6aa8-4395-a29a-6b3f94ccf2bc'	System	11 Nov 2020 18:00:54
User entered '11 Nov 2020 12:00'	System	11 Nov 2020 18:00:54

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(65)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:21:09

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	10 Nov 2020 18:03:25
User entered 'Day 66'	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:39', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'dfe81b31-fc3e-4c43-8e52-d4a6aee5a712'	System	12 Nov 2020 18:00:45
User entered 'No (N)'	System	12 Nov 2020 18:00:45



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-12T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'dfe81b31-fc3e-4c43-8e52-d4a6aee5a712'	System	12 Nov 2020 18:00:45
User entered '12 Nov 2020 12:00'	System	12 Nov 2020 18:00:45

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(66)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:03:25

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Nov 2020 18:00:27
User entered 'Day 67'	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cfefdc94-cae6-4f05-8aa6-123118353198'	System	13 Nov 2020 18:38:30
User entered 'No (N)'	System	13 Nov 2020 18:38:30

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-13T12:38:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'cfefdc94-cae6-4f05-8aa6-123118353198'	System	13 Nov 2020 18:38:30
User entered '13 Nov 2020 12:38'	System	13 Nov 2020 18:38:30

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 18:00:27

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(67)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 18:00:27



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	12 Nov 2020 18:00:28
User entered 'Day 68'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:33:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b6a6f3d0-b237-4912-936b-2c1e0c2ed349' User entered 'No (N)'	System	15 Nov 2020 09:46:59
	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-14T12:34:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b6a6f3d0-b237-4912-936b-2c1e0c2ed349' User entered '14 Nov 2020 12:34'	System	15 Nov 2020 09:46:59
	System	15 Nov 2020 09:46:59

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(68)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	13 Nov 2020 18:38:05
User entered 'Day 69'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd0b834c9-3cd7-4365-9081-70985fdbdb87'	System	15 Nov 2020 18:00:52
User entered 'No (N)'	System	15 Nov 2020 18:00:52

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T12:00:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'd0b834c9-3cd7-4365-9081-70985fdbdb87'	System	15 Nov 2020 18:00:52
User entered '15 Nov 2020 12:00'	System	15 Nov 2020 18:00:52



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(69)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 18:38:05

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 09:46:57
User entered 'Day 70'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '87e46b57-ad22-4713-9c3d-da99772a5e29'	System	16 Nov 2020 18:00:50
User entered 'No (N)'	System	16 Nov 2020 18:00:50

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '87e46b57-ad22-4713-9c3d-da99772a5e29'	System	16 Nov 2020 18:00:50
User entered '16 Nov 2020 12:00'	System	16 Nov 2020 18:00:50

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 09:46:57
User entered 'Day 70'	System	15 Nov 2020 09:46:57



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:00:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f1db0ec8-4398-4a1d-8568-d68c24a63b75' User entered 'No (N)'	System	16 Nov 2020 18:01:07
	System	16 Nov 2020 18:01:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-16T12:01:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f1db0ec8-4398-4a1d-8568-d68c24a63b75' User entered '16 Nov 2020 12:01'	System	16 Nov 2020 18:01:07
	System	16 Nov 2020 18:01:07

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(70)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 09:46:57

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	15 Nov 2020 18:00:28
User entered 'Day 71'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2f0e388f-bd2f-410c-a472-c493dff75437'	System	17 Nov 2020 23:33:51
User entered 'No (N)'	System	17 Nov 2020 23:33:51

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-17T17:33:46', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2f0e388f-bd2f-410c-a472-c493dff75437'	System	17 Nov 2020 23:33:51
User entered '17 Nov 2020 17:33'	System	17 Nov 2020 23:33:51

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:00:28



US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(72)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:00:28

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	16 Nov 2020 18:00:22
User entered 'Day 72'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:28:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6e8a8f85-143e-4147-9d8c-2ae7e15ad5c7'	System	18 Nov 2020 22:28:18
User entered 'No (N)'	System	18 Nov 2020 22:28:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-18T16:28:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '6e8a8f85-143e-4147-9d8c-2ae7e15ad5c7'	System	18 Nov 2020 22:28:18
User entered '18 Nov 2020 16:28'	System	18 Nov 2020 22:28:18

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:00:22

US3292128

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(73)

Generated On: 09 Jun 2021 16:22:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:00:22

US3292128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:05:25
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	16 Sep 2020 18:21:58

**US3292128**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:05:25
User entered '16 Sep 2020'	Kristy Trevino (b) (4)	16 Sep 2020 18:21:58



US3292128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:05:25
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	16 Sep 2020 18:21:58

US3292128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:05:25
User entered empty.	Kristy Trevino (b) (4)	16 Sep 2020 18:21:58

US3292128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:05:31
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	16 Sep 2020 18:22:05

US3292128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	16 Sep 2020 18:22:05

US3292128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		25 Feb 2021 16:03:48
User closed query 'Data missing in eSource. Please reconcile' (Site from CRA).		25 Feb 2021 16:03:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
Query 'Data missing in eSource. Please reconcile' answered with 'No visit was conducted 1 attempt made' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
User opened query 'Data missing in eSource. Please reconcile' (Site from CRA).		18 Feb 2021 20:33:18
User entered 'Yes (Y)'		16 Dec 2020 18:07:14
		23 Sep 2020 16:42:25

US3292128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		25 Feb 2021 16:03:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:42:25

US3292128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User closed query 'Per source, contact was not made. Please reconcile' (Site from CRA). DataPoint Verified.		08 Apr 2021 19:02:23 08 Apr 2021 19:02:13
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Query 'Per source, contact was not made. Please reconcile' answered with 'Reconciled. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:38:15
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 18:37:36
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error		01 Apr 2021 18:37:36
User opened query 'Per source, contact was not made. Please reconcile' (Site from CRA).		25 Feb 2021 16:05:26
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:42:25

US3292128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:02:22
User signature succeeded.	(b) (4)	08 Apr 2021 16:15:38
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System). DataPoint Un-verified.	(b) (4) System	01 Apr 2021 18:38:54
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 18:38:54
User entered 'Contact attempted once in error, call not conducted.' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Apr 2021 18:38:54
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System). DataPoint Verified.	System	01 Apr 2021 18:37:36
User signature succeeded.	(b) (4), (b) (6)	25 Feb 2021 16:05:29
User entered empty.	Douglas Denham (b) (4) (b) (4) (b) (4), (b) (6)	22 Feb 2021 18:47:50 23 Sep 2020 16:42:25



US3292128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:42:59

US3292128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	23 Sep 2020 16:42:59

**US3292128**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:07:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 16:18:52

**US3292128**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:07:53
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 16:18:52

US3292128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:07:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 16:18:52

US3292128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:07:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:18:52

US3292128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:08:08
User entered 'Yes (Y)'		30 Sep 2020 16:18:56

US3292128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	30 Sep 2020 16:18:56



US3292128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:40:28

**US3292128**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:22:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:10:39
User entered '6 Oct 2020'		06 Oct 2020 15:40:28

US3292128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:10:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 15:40:28

US3292128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'VISIT3'	System	06 Oct 2020 15:40:28

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered '08:23'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '6 Oct 2020 08:23'	System	06 Oct 2020 15:41:31



US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:11:16
User entered '36.6' C		06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:41:31

**US3292128**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:11:16
User entered '57'		06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'bpm'	System	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered '16'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'breaths/min'	System	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered '133'	(b) (4), (b) (6)	06 Oct 2020 15:41:31



US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4)	13 Jan 2021 20:11:16
User entered '79'	(b) (4), (b) (6)	06 Oct 2020 15:41:31

**US3292128**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'mmHg'	System	06 Oct 2020 15:41:31

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20

US3292128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20

US3292128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		12 Apr 2021 19:24:13
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:42

US3292128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		12 Apr 2021 19:24:13
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:56
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:41:42

US3292128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		12 Apr 2021 19:24:27
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:41:59



US3292128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		12 Apr 2021 19:24:27
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:56
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:41:59

**US3292128**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:22:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
DataPoint Verified.		12 Apr 2021 19:24:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
User entered '08:27'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:59

US3292128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered '6 Oct 2020 08:27'	System	06 Oct 2020 15:41:59

US3292128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:11:54
User entered 'Yes (Y)'		06 Oct 2020 15:42:12

**US3292128**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	06 Oct 2020 15:42:12

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 64'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:47:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '629066b8-2e5c-4e57-85df-8f4078c2762e' User entered 'No (N)'	System	11 Oct 2020 17:47:51
	System	11 Oct 2020 17:47:51

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:47:43', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '629066b8-2e5c-4e57-85df-8f4078c2762e'	System	11 Oct 2020 17:47:51
User entered 'No (N)'	System	11 Oct 2020 17:47:51



**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-11T12:47:47', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '629066b8-2e5c-4e57-85df-8f4078c2762e' User entered '11 Oct 2020 12:47:47'	System	11 Oct 2020 17:47:51
	System	11 Oct 2020 17:47:51

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 71'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:16:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3bce6cb1-fc49-47aa-9916-24a31089add2'	System	18 Oct 2020 14:16:40
User entered 'No (N)'	System	18 Oct 2020 14:16:40

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:16:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3bce6cb1-fc49-47aa-9916-24a31089add2'	System	18 Oct 2020 14:16:40
User entered 'No (N)'	System	18 Oct 2020 14:16:40

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-18T09:16:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3bce6cb1-fc49-47aa-9916-24a31089add2' User entered '18 Oct 2020 09:16:32'	System	18 Oct 2020 14:16:40
	System	18 Oct 2020 14:16:40

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:27:07



**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 78'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-25T04:43:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ee6d043-546c-4bc0-b58c-fdd68cf31552'	System	25 Oct 2020 09:43:29
User entered 'No (N)'	System	25 Oct 2020 09:43:29

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-25T04:43:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ee6d043-546c-4bc0-b58c-fdd68cf31552'	System	25 Oct 2020 09:43:29
User entered 'No (N)'	System	25 Oct 2020 09:43:29

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-10-25T04:43:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8ee6d043-546c-4bc0-b58c-fdd68cf31552' User entered '25 Oct 2020 04:43:24'	System	25 Oct 2020 09:43:29
	System	25 Oct 2020 09:43:29

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 92'	System	11 Aug 2020 19:27:07



US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-08T05:40:20', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7785cc7-d45f-4811-b0f1-91f72873db8d'	System	08 Nov 2020 11:41:01
User entered 'Yes (Y)'	System	08 Nov 2020 11:41:01

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-08T05:40:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7785cc7-d45f-4811-b0f1-91f72873db8d'	System	08 Nov 2020 11:41:01
User entered 'No (N)'	System	08 Nov 2020 11:41:01

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-08T05:40:34', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7785cc7-d45f-4811-b0f1-91f72873db8d'	System	08 Nov 2020 11:41:01
User entered 'No (N)'	System	08 Nov 2020 11:41:01

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-08T05:40:55', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7785cc7-d45f-4811-b0f1-91f72873db8d'	System	08 Nov 2020 11:41:01
User entered 'No (N)'	System	08 Nov 2020 11:41:01

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-08T05:40:58', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b7785cc7-d45f-4811-b0f1-91f72873db8d' User entered '08 Nov 2020 05:40:58'	System	08 Nov 2020 11:41:01
	System	08 Nov 2020 11:41:01

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:27:07

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:27:07

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered 'Day 99'	System	11 Aug 2020 19:27:07



US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T03:46:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7080f7a-d08d-49b3-9ab5-4e0db47ac6a8'	System	15 Nov 2020 09:47:11
User entered 'No (N)'	System	15 Nov 2020 09:47:11

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T03:47:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7080f7a-d08d-49b3-9ab5-4e0db47ac6a8'	System	15 Nov 2020 09:47:11
User entered 'No (N)'	System	15 Nov 2020 09:47:11

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-15T03:47:07', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'c7080f7a-d08d-49b3-9ab5-4e0db47ac6a8' User entered '15 Nov 2020 03:47:07'	System	15 Nov 2020 09:47:11
	System	15 Nov 2020 09:47:11

US3292128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:27:07

**US3292128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:53:04
Data entry locked.	System	11 Aug 2020 19:27:07
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:27:07

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-20T06:58:11', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '69e4d175-ca88-4517-9b7b-fdd1fd0cacf5'	System	20 Nov 2020 12:58:25
User entered 'No (N)'	System	20 Nov 2020 12:58:25

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-20T06:58:16', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '69e4d175-ca88-4517-9b7b-fdd1fd0cacf5'	System	20 Nov 2020 12:58:25
User entered 'No (N)'	System	20 Nov 2020 12:58:25



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-20T06:58:19', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '69e4d175-ca88-4517-9b7b-fdd1fd0cacf5'	System	20 Nov 2020 12:58:25
User entered '20 Nov 2020 06:58:19'	System	20 Nov 2020 12:58:25

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-26T04:42:05', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef44b9c8-1ea8-45a7-94eb-c678bd0e2405' User entered 'No (N)'	System	26 Nov 2020 10:42:20

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-26T04:42:12', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef44b9c8-1ea8-45a7-94eb-c678bd0e2405'	System	26 Nov 2020 10:42:20
User entered 'No (N)'	System	26 Nov 2020 10:42:20

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-11-26T04:42:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ef44b9c8-1ea8-45a7-94eb-c678bd0e2405'	System	26 Nov 2020 10:42:20
User entered '26 Nov 2020 04:42:17'	System	26 Nov 2020 10:42:20

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:59:48

US3292128

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-03T05:00:48', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfa22d68-9035-4dd1-9639-02676572ab74' User entered 'No (N)'	System	03 Dec 2020 11:01:05

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-03T05:00:57', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfa22d68-9035-4dd1-9639-02676572ab74'	System	03 Dec 2020 11:01:05
User entered 'No (N)'	System	03 Dec 2020 11:01:05

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-03T05:01:02', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'bfa22d68-9035-4dd1-9639-02676572ab74'	System	03 Dec 2020 11:01:05
User entered '03 Dec 2020 05:01:02'	System	03 Dec 2020 11:01:05

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:59:48



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-10T04:54:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ec31ca00-afc0-4d49-b4eb-f57a975c44de' User entered 'No (N)'	System	10 Dec 2020 10:54:48
	System	10 Dec 2020 10:54:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-10T04:54:41', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ec31ca00-afc0-4d49-b4eb-f57a975c44de' User entered 'No (N)'	System	10 Dec 2020 10:54:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-10T04:54:45', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ec31ca00-afc0-4d49-b4eb-f57a975c44de' User entered '10 Dec 2020 04:54:45'	System	10 Dec 2020 10:54:48
	System	10 Dec 2020 10:54:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-19T12:00:17', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f17ae07b-e33a-436c-99a7-cdb8730f85b3' User entered 'No (N)'	System	19 Dec 2020 18:00:39
	System	19 Dec 2020 18:00:39

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-19T12:00:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f17ae07b-e33a-436c-99a7-cdb8730f85b3' User entered 'No (N)'	System	19 Dec 2020 18:00:39
	System	19 Dec 2020 18:00:39



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-19T12:00:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f17ae07b-e33a-436c-99a7-cdb8730f85b3' User entered '19 Dec 2020 12:00:28'	System	19 Dec 2020 18:00:39
	System	19 Dec 2020 18:00:39

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-26T07:23:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '465a7e28-c8ec-4fd2-ba86-39fe3db65001' User entered 'No (N)'	System	26 Dec 2020 13:23:40
	System	26 Dec 2020 13:23:40

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-26T07:23:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '465a7e28-c8ec-4fd2-ba86-39fe3db65001'	System	26 Dec 2020 13:23:40
User entered 'No (N)'	System	26 Dec 2020 13:23:40

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2020-12-26T07:23:36', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '465a7e28-c8ec-4fd2-ba86-39fe3db65001' User entered '26 Dec 2020 07:23:36'	System	26 Dec 2020 13:23:40
	System	26 Dec 2020 13:23:40

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-02T08:40:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f98fa7d-5d13-4b67-bd8a-584c18391eaf' User entered 'No (N)'	System	02 Jan 2021 14:40:37
	System	02 Jan 2021 14:40:37

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-02T08:40:32', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f98fa7d-5d13-4b67-bd8a-584c18391eaf'	System	02 Jan 2021 14:40:37
User entered 'No (N)'	System	02 Jan 2021 14:40:37

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-02T08:40:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f98fa7d-5d13-4b67-bd8a-584c18391eaf' User entered '02 Jan 2021 08:40:35'	System	02 Jan 2021 14:40:37
	System	02 Jan 2021 14:40:37

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:59:48



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-08T12:03:10', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5e4f5ac9-d519-45d9-bfb7-de760b289d9e' User entered 'No (N)'	System	08 Jan 2021 18:03:21
	System	08 Jan 2021 18:03:21

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-08T12:03:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5e4f5ac9-d519-45d9-bfb7-de760b289d9e' User entered 'No (N)'	System	08 Jan 2021 18:03:21
	System	08 Jan 2021 18:03:21

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-08T12:03:18', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5e4f5ac9-d519-45d9-bfb7-de760b289d9e' User entered '08 Jan 2021 12:03:18'	System	08 Jan 2021 18:03:21
	System	08 Jan 2021 18:03:21

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-14T06:19:25', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5a60bc8d-047e-4967-ab75-204ee35c39ab' User entered 'No (N)'	System	14 Jan 2021 12:19:36
	System	14 Jan 2021 12:19:36

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-14T06:19:29', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5a60bc8d-047e-4967-ab75-204ee35c39ab' User entered 'No (N)'	System	14 Jan 2021 12:19:36
	System	14 Jan 2021 12:19:36



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-14T06:19:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '5a60bc8d-047e-4967-ab75-204ee35c39ab' User entered '14 Jan 2021 06:19:33'	System	14 Jan 2021 12:19:36
	System	14 Jan 2021 12:19:36

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-21T10:22:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f7581d0-8730-452a-823d-61d60126f71b' User entered 'No (N)'	System	21 Jan 2021 16:22:16
	System	21 Jan 2021 16:22:16

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-21T10:22:09', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f7581d0-8730-452a-823d-61d60126f71b' User entered 'No (N)'	System	21 Jan 2021 16:22:16
	System	21 Jan 2021 16:22:16

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-21T10:22:14', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '0f7581d0-8730-452a-823d-61d60126f71b' User entered '21 Jan 2021 10:22:14'	System	21 Jan 2021 16:22:16
	System	21 Jan 2021 16:22:16

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-28T05:47:27', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ae36ef15-d7b0-4e34-a943-dda18ad43f2e' User entered 'No (N)'	System	28 Jan 2021 11:47:38
	System	28 Jan 2021 11:47:38

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-28T05:47:31', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ae36ef15-d7b0-4e34-a943-dda18ad43f2e' User entered 'No (N)'	System	28 Jan 2021 11:47:38

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-01-28T05:47:35', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'ae36ef15-d7b0-4e34-a943-dda18ad43f2e' User entered '28 Jan 2021 05:47:35'	System	28 Jan 2021 11:47:38
	System	28 Jan 2021 11:47:38

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-04T05:25:42', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4807c088-f581-4134-ba2f-503c657232df' User entered 'No (N)'	System	04 Feb 2021 11:26:23

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-04T05:25:59', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4807c088-f581-4134-ba2f-503c657232df' User entered 'No (N)'	System	04 Feb 2021 11:26:23

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-04T05:26:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '4807c088-f581-4134-ba2f-503c657232df' User entered '04 Feb 2021 05:26:03'	System	04 Feb 2021 11:26:23
	System	04 Feb 2021 11:26:23

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-11T05:15:03', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8fd57e44-2a96-4fc9-9abb-08c0da0a9564' User entered 'No (N)'	System	11 Feb 2021 11:15:35
	System	11 Feb 2021 11:15:35

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-11T05:15:28', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8fd57e44-2a96-4fc9-9abb-08c0da0a9564' User entered 'No (N)'	System	11 Feb 2021 11:15:35



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-11T05:15:33', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '8fd57e44-2a96-4fc9-9abb-08c0da0a9564' User entered '11 Feb 2021 05:15:33'	System	11 Feb 2021 11:15:35
	System	11 Feb 2021 11:15:35

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-18T05:15:15', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '09bb712e-0246-42ef-91a2-db5b789df868' User entered 'No (N)'	System	18 Feb 2021 11:15:27
	System	18 Feb 2021 11:15:27

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-18T05:15:21', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '09bb712e-0246-42ef-91a2-db5b789df868' User entered 'No (N)'	System	18 Feb 2021 11:15:27

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-18T05:15:24', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '09bb712e-0246-42ef-91a2-db5b789df868' User entered '18 Feb 2021 05:15:24'	System	18 Feb 2021 11:15:27
	System	18 Feb 2021 11:15:27

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-25T05:50:22-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b06a5b19-3422-4f29-a177-06604b647031' User entered 'No (N)'	System	25 Feb 2021 11:50:51
	System	25 Feb 2021 11:50:51

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-25T05:50:44-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b06a5b19-3422-4f29-a177-06604b647031' User entered 'No (N)'	System	25 Feb 2021 11:50:51
	System	25 Feb 2021 11:50:51

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-25T05:50:49-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b06a5b19-3422-4f29-a177-06604b647031'	System	25 Feb 2021 11:50:51
User entered '25 Feb 2021 11:50:49'	System	25 Feb 2021 11:50:51

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:59:48



US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-04T00:22:42-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2ad88057-8b12-42c2-b098-9a3d8fbfeaa'	System	04 Mar 2021 06:22:58
User entered 'No (N)'	System	04 Mar 2021 06:22:58

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-04T00:22:48-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2ad88057-8b12-42c2-b098-9a3d8fbfeaaaf'	System	04 Mar 2021 06:22:58
User entered 'No (N)'	System	04 Mar 2021 06:22:58

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-04T00:22:53-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '2ad88057-8b12-42c2-b098-9a3d8fbfeaaf' User entered '04 Mar 2021 00:22:53'	System	04 Mar 2021 06:22:58
	System	04 Mar 2021 06:22:58

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-13T11:49:37-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b3c07db8-e333-4bd3-b479-1ff196863bbc' User entered 'No (N)'	System	13 Mar 2021 17:49:50
	System	13 Mar 2021 17:49:50

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-13T11:49:42-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b3c07db8-e333-4bd3-b479-1ff196863bbc' User entered 'No (N)'	System	13 Mar 2021 17:49:50
	System	13 Mar 2021 17:49:50



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-13T11:49:48-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b3c07db8-e333-4bd3-b479-1ff196863bbc' User entered '13 Mar 2021 11:49:48'	System	13 Mar 2021 17:49:50
	System	13 Mar 2021 17:49:50

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-18T10:10:57-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '288ac275-5c46-42f8-aa88-ec68e613603f' User entered 'No (N)'	System	18 Mar 2021 15:11:09
	System	18 Mar 2021 15:11:09

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-18T10:11:01-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '288ac275-5c46-42f8-aa88-ec68e613603f' User entered 'No (N)'	System	18 Mar 2021 15:11:09

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-18T10:11:04-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '288ac275-5c46-42f8-aa88-ec68e613603f' User entered '18 Mar 2021 10:11:04'	System	18 Mar 2021 15:11:09
	System	18 Mar 2021 15:11:09

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:59:48

US3292128

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-25T05:57:08-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9608cc1b-0182-44f1-b36a-df2fde4bb0ef' User entered 'No (N)'	System	25 Mar 2021 10:57:27
	System	25 Mar 2021 10:57:27

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-25T05:57:21-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9608cc1b-0182-44f1-b36a-df2fde4bb0ef' User entered 'No (N)'	System	25 Mar 2021 10:57:27

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-03-25T05:57:25-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '9608cc1b-0182-44f1-b36a-df2fde4bb0ef' User entered '25 Mar 2021 05:57:25'	System	25 Mar 2021 10:57:27
	System	25 Mar 2021 10:57:27

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-01T07:54:10-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '20ee2382-5df7-499f-995d-e4669b3c2464'	System	01 Apr 2021 12:54:20
User entered 'No (N)'	System	01 Apr 2021 12:54:20

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-01T07:54:13-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '20ee2382-5df7-499f-995d-e4669b3c2464'	System	01 Apr 2021 12:54:20
User entered 'No (N)'	System	01 Apr 2021 12:54:20

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-01T07:54:17-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '20ee2382-5df7-499f-995d-e4669b3c2464'	System	01 Apr 2021 12:54:20
User entered '01 Apr 2021 07:54:17'	System	01 Apr 2021 12:54:20

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:59:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-09T07:49:00-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f71da09e-93a3-48f4-9d13-42d4ccc36a4a' User entered 'No (N)'	System	09 Apr 2021 12:49:15
	System	09 Apr 2021 12:49:15

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-09T07:49:06-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f71da09e-93a3-48f4-9d13-42d4ccc36a4a' User entered 'No (N)'	System	09 Apr 2021 12:49:15



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-09T07:49:09-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'f71da09e-93a3-48f4-9d13-42d4ccc36a4a'	System	09 Apr 2021 12:49:15
User entered '09 Apr 2021 07:49:09'	System	09 Apr 2021 12:49:15

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-17T07:05:37-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '704c4e46-5234-4c0a-ba28-c50b4cc8d8e1' User entered 'No (N)'	System	17 Apr 2021 12:05:48
	System	17 Apr 2021 12:05:48

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-17T07:05:42-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '704c4e46-5234-4c0a-ba28-c50b4cc8d8e1' User entered 'No (N)'	System	17 Apr 2021 12:05:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-17T07:05:46-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '704c4e46-5234-4c0a-ba28-c50b4cc8d8e1' User entered '17 Apr 2021 07:05:46'	System	17 Apr 2021 12:05:48
	System	17 Apr 2021 12:05:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-22T06:44:04-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3038785b-b067-42dd-b1be-41c6d89eae02'	System	22 Apr 2021 11:44:15
User entered 'No (N)'	System	22 Apr 2021 11:44:15

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-22T06:44:08-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3038785b-b067-42dd-b1be-41c6d89eae02'	System	22 Apr 2021 11:44:15
User entered 'No (N)'	System	22 Apr 2021 11:44:15

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-22T06:44:11-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: '3038785b-b067-42dd-b1be-41c6d89eae02'	System	22 Apr 2021 11:44:15
User entered '22 Apr 2021 06:44:11'	System	22 Apr 2021 11:44:15

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-29T05:04:27-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e25ef504-a829-4c99-8b7d-5ed6c30afb59'	System	30 Apr 2021 13:53:00
User entered 'No (N)'	System	30 Apr 2021 13:53:00

US3292128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:59

Have you been exposed to someone with 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 (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-29T05:04:30-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e25ef504-a829-4c99-8b7d-5ed6c30afb59' User entered 'No (N)'	System	30 Apr 2021 13:53:00

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-04-29T05:04:33-05:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'e25ef504-a829-4c99-8b7d-5ed6c30afb59'	System	30 Apr 2021 13:53:00
User entered '29 Apr 2021 05:04:33'	System	30 Apr 2021 13:53:00

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:59:48

**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:59:48



**US3292128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:22:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:59:48

US3292128

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:22:59**

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)	25 Apr 2021 22:45:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-27T07:54:17-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b444da33-a27b-4af7-abff-72ffec078c48'	System	27 Feb 2021 13:54:28
User entered 'No (N)'	System	27 Feb 2021 13:54:28

US3292128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:22:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:45:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BA8ECD5-957D-4394-A512-FA143B067D30)', Time: '2021-02-27T07:54:27-06:00', User OID: 'PatientReportedOutcome (US3292128)', ODM File OID: 'b444da33-a27b-4af7-abff-72ffec078c48'	System	27 Feb 2021 13:54:28
User entered '27 Feb 2021 13:54:27'	System	27 Feb 2021 13:54:28

**US3292128**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:09:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 18:19:04

US3292128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:09:56
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 18:19:04

US3292128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:09:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 18:19:04

US3292128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:09:56
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 18:19:04

US3292128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	16 Dec 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 18:24:45



US3292128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:20
User entered 'l'	System	03 Nov 2020 18:24:45

US3292128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Dec 2020 20:58:39

US3292128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	5 Apr 2021 03:50:53
DataPoint Verified.		5 Mar 2021 15:08:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '7 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Dec 2020 20:58:39

US3292128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Dec 2020 20:58:39

US3292128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Dec 2020 20:58:39

US3292128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Dec 2020 20:58:43

**US3292128**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
User entered 'l'	System	08 Dec 2020 20:58:43

**US3292128**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 16:06:12



US3292128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:06:12

US3292128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 16:06:12

US3292128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:08:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:06:12

US3292128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:09:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	27 Jan 2021 20:51:05

**US3292128**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
User entered 'l'	System	27 Jan 2021 20:51:05

US3292128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:09:36
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:55:42

US3292128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:09:36
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '5 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:55:42

US3292128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	5 Apr 2021 03:50:53
DataPoint Verified.		5 Mar 2021 15:09:36
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:55:42



**US3292128**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:09:36
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:55:42

US3292128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
DataPoint Verified.		05 Mar 2021 15:09:57
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:55:45

**US3292128**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:50:53
User entered 'l'	System	08 Feb 2021 20:55:45

US3292128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:37
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:21

US3292128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:37
User entered '1 Mar 2021'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:21

US3292128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:37
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:21

US3292128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered 'VISIT4'	System	29 Mar 2021 15:44:21

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered 'No (N)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26



US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered empty.	System	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered empty.	System	29 Mar 2021 15:44:26



US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered empty.	System	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered empty.	System	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:41
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered empty.	System	29 Mar 2021 15:44:26

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34

US3292128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34



US3292128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:01
User entered 'No (N)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:29

US3292128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:01
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 15:44:29

US3292128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:43
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:39

US3292128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:43
User entered '1 Mar 2021'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:39

US3292128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:43
User entered '08:00'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:39

US3292128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered '1 Mar 2021 08:00'	System	29 Mar 2021 15:44:39

US3292128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:38:48
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	29 Mar 2021 15:44:41

US3292128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:50:34
User entered 'I'	System	29 Mar 2021 15:44:41



**US3292128**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:15:51

US3292128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:15:51

US3292128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:15:51

US3292128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:15:51

US3292128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:15:54

**US3292128**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 21:15:54

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:04:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:48:51

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:04:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:48:51



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[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 13:15:28
DataPoint Verified.		19 Apr 2021 17:04:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 18:48:51

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 18:48:51

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07

**US3292128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:22:59**

[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 13:15:28
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:47

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:47

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:05:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:22:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'I'	System	20 Jan 2021 18:49:07

**US3292128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:22:59**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'I'	System	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	20 Jan 2021 18:50:35
DataPoint set to visible.	System	20 Jan 2021 18:49:07



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	20 Jan 2021 18:50:35
DataPoint set to visible.	System	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User accepted default value 'Pre-Dose (PREDOSE)'		20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '08:10'	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '19 Jan 2021 08:10'	System	20 Jan 2021 18:50:35



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 10:10:59
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gerardo Pena (b) (4)	25 Jan 2021 17:12:00
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Jan 2021 18:50:35
User entered '35.8' C	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '62'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'bpm'	System	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:08
User closed query 'Per source, Value is 16' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:38:37
DataPoint Verified.	(b) (4)	20 Apr 2021 19:38:35
Query 'Per source, Value is 16' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	20 Apr 2021 14:57:15
Signature has been broken.	(b) (4)	(b) (4)
User entered '16' reason for change: Data Entry Error	Dawn Killian (b) (4)	20 Apr 2021 14:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:43
DataPoint Verified.	(b) (4)	19 Apr 2021 17:11:38
User opened query 'Per source, Value is 16' (Site from CRA).	(b) (4)	19 Apr 2021 17:11:16
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '12'	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'breaths/min'	System	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '139'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '84'	(b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	20 Jan 2021 18:50:35
DataPoint set to visible.	System	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User accepted default value 'Post-Dose (POSTDOSE)'		20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '10:14'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '19 Jan 2021 10:14'	System	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '60'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'bpm'	System	20 Jan 2021 18:52:52



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'breaths/min'	System	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '121'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:11:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '63'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	20 Jan 2021 18:52:52

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:12:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:12:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:07



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

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)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mRNA-1273'	System	20 Jan 2021 18:53:24
DataPoint set to visible.	System	20 Jan 2021 18:49:07

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '09:44'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '19 Jan 2021 09:44'	System	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:13:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Jan 2021 18:53:24



US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:13:54
User entered 'ONCE'		20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 18:53:24

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:14:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:49:23

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:14:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:23

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:14:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '08:27'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:23

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '19 Jan 2021 08:27'	System	20 Jan 2021 18:49:23

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:14:16
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:14:16
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:49:35



**US3292128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:22:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:14:16
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '08:35'	(b) (4), (b) (6)	20 Jan 2021 18:49:35

**US3292128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:22:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '19 Jan 2021 08:35'	System	20 Jan 2021 18:49:35

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:53:31

US3292128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'I'	System	20 Jan 2021 18:53:31

US3292128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		05 Mar 2021 15:10:49
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:44

**US3292128**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:10:49
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:44

**US3292128**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		05 Mar 2021 15:10:49
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Jan 2021 20:59:44

US3292128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:10:49
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:44



US3292128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		05 Mar 2021 15:10:55
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:00:09

US3292128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'l'	System	27 Jan 2021 21:00:09

**US3292128**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:22:59**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'I'	System	27 Jan 2021 21:00:09
DataPoint set to visible.	System	27 Jan 2021 21:00:09

US3292128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:54
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:00:59

US3292128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:19:54
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '26 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:00:59

US3292128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[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 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:54
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:00:59

US3292128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'OLD29'	System	26 Feb 2021 16:00:59

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44



US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '26 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '07:35'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '26 Feb 2021 07:35'	System	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '36.5' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

**US3292128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:22:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '60'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44



**US3292128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'bpm'	System	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '16'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'breaths/min'	System	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '117'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '67'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	26 Feb 2021 16:01:44

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16



US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '26 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '09:16'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '26 Feb 2021 09:16'	System	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '36.1' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '56'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16



**US3292128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'bpm'	System	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '16'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'breaths/min'	System	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '133'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:28
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '80'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mmHg'	System	26 Feb 2021 16:02:16

US3292128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:44
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:30



US3292128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:20:44
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '26 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:30

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

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)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

**US3292128**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:22:59**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'mRNA-1273'	System	26 Feb 2021 16:02:45
DataPoint set to visible.	System	27 Jan 2021 21:00:09

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '26 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered '08:45'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '26 Feb 2021 08:45'	System	26 Feb 2021 16:02:45



US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:22:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:22:04
User entered 'ONCE'	System	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 16:02:45

US3292128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		19 Apr 2021 17:22:07
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Feb 2021 16:02:55

US3292128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'l'	System	26 Feb 2021 16:02:55

**US3292128**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:00:31
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 13:32:31

**US3292128**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:00:31
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 13:32:31

**US3292128**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:22:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:00:31
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 13:32:31



US3292128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:00:31
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 13:32:31

US3292128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:00:35
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 13:32:59

US3292128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'l'	System	06 Mar 2021 13:32:59

US3292128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:52
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:22

US3292128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:52
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '26 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:22

US3292128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[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 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:52
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:22

US3292128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered 'OLD57'	System	29 Mar 2021 15:37:22

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28



US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

**US3292128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	29 Mar 2021 15:37:28
	(b) (4)	

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

**US3292128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:22:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	29 Mar 2021 15:37:28



US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.		09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered empty.	System	29 Mar 2021 15:37:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28

US3292128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28



US3292128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:37:03
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:33

US3292128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:37:03
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:33

US3292128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:37:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:41

US3292128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4)	09 Apr 2021 19:37:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '26 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:41

US3292128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:37:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '07:48'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:37:41

**US3292128**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:22:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:28
User entered '26 Mar 2021 07:48'	System	29 Mar 2021 15:37:41

US3292128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:22:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:27
User closed query 'Per DM: 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', 'Joint aches in several joints' and 'Muscle aches all over' 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)	22 Apr 2021 14:41:36
Query 'Per DM: 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', 'Joint aches in several joints' and 'Muscle aches all over' 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 'Per verbal from subject, he states he has a hx of aches and pains due to his surgical hx (rotator cuff repair) sx did not develop after injection. AE not required. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:20:44
User opened query 'Per DM: 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', 'Joint aches in several joints' and 'Muscle aches all over' 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 17:11:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:01
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Signature has been broken.	(b) (4) Nathan Cortez (b) (4)	05 Mar 2021 22:46:57

US3292128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:22:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Nathan Cortez (b) (4)	05 Mar 2021 22:46:57
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'No (N)'	Dawn Killian (b) (4)	03 Feb 2021 22:08:43



US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 16:45:34
Reviewed for Safety.		08 Mar 2021 16:07:27
User entered	System	08 Mar 2021 16:07:24
'USA-US072-2021-mRNA-1273-P301000016'		
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 16:07:24

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:36
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:59:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:59:59
Data point term sent to Coder	System	05 Mar 2021 22:51:01
User entered 'Dog Bite R Arm'	Nathan Cortez (b) (4) (b) (4)	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:37
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:39
User entered 'No (N)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:16
DataPoint Un-verified.		19 Apr 2021 20:39:14
User closed query 'Per source, answer is yes. Please review and reconcile.' (Site from CRA).		16 Apr 2021 20:37:52
DataPoint Verified.		16 Apr 2021 20:37:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
Query 'Per source, answer is yes. Please review and reconcile.' answered with 'Source has been updated' (Site from CRA).	(b) (4), (b) (6)	11 Apr 2021 13:37:15
User opened query 'Per source, answer is yes. Please review and reconcile.' (Site from CRA).		09 Apr 2021 16:42:16
User entered 'No (N)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:41
User entered '03 Mar 2021'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:42
User entered empty.	Nathan Cortez (u) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:50:07



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:39:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	22 Apr 2021 18:05:08
	Antonio Gutierrez (b) (4)	22 Apr 2021 18:05:08
Signature has been broken.	Antonio Gutierrez (b) (4)	22 Apr 2021 18:05:08
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Apr 2021 18:05:08
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Apr 2021 18:04:42
User closed query 'Per source, AE is ongoing. Please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:37:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Apr 2021 13:39:09
Query 'Per source, AE is ongoing. Please review and reconcile' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	11 Apr 2021 13:38:20
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Apr 2021 13:37:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 13:37:44
User opened query 'Per source, AE is ongoing. Please review and reconcile' (Site from CRA).		09 Apr 2021 16:42:52
User entered 'No (N)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:40:01
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:18:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	22 Apr 2021 18:05:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
Signature has been broken.	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
User entered '1 Apr 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:02:09
DataPoint Verified.		16 Apr 2021 20:38:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 12:54:35
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'Updated' (Site from System).		11 Apr 2021 13:40:12
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		11 Apr 2021 13:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 13:39:09
DataPoint Un-verified.		09 Apr 2021 16:45:46
DataPoint Verified.		09 Apr 2021 16:45:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Mar 2021'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Per source, AE is grade 2. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:35:17
		16 Apr 2021 20:35:16
User signature succeeded.	(b) (4)	16 Apr 2021 14:03:14
Query 'Per source, AE is grade 2. Please review and reconcile. ' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	11 Apr 2021 13:41:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error		11 Apr 2021 13:39:46
User opened query 'Per source, AE is grade 2. Please review and reconcile. ' (Site from CRA).		09 Apr 2021 16:44:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:52
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:53
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07



**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:55
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	11 Apr 2021 13:43:04
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	11 Apr 2021 13:43:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:56
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	05 Mar 2021 22:50:07
User entered 'I'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:26
User entered '4 Mar 2021'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:20:38
DataPoint Un-verified.		19 Apr 2021 20:39:23
Query 'Please provide discharge date in source' canceled (Site from CRA).		19 Apr 2021 20:37:59
DataPoint Verified.		19 Apr 2021 20:37:57
User opened query 'Please provide discharge date in source' (Site from CRA).		16 Apr 2021 20:39:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:16:42
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).		11 Apr 2021 13:43:24
DataPoint Un-verified.		11 Apr 2021 13:43:04
User entered '5 Mar 2021' reason for change: Data Entry Error		11 Apr 2021 13:43:04
DataPoint Verified.		09 Apr 2021 16:46:01
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		12 Mar 2021 19:47:46
User entered empty.	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:30
User entered 'No (N)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:03
User entered empty.	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:04
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:06
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:07
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:44:24
User entered 'Not Related (NOT RELATED)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:44:25
User entered 'Not Related (NOT RELATED)'	Nathan Cortez (u) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:59:00
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
User closed query 'PV Re-Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:15:39
Query 'PV Re-Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	22 Apr 2021 14:42:18
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	22 Apr 2021 14:42:06
Signature has been broken.	Antonio Gutierrez (b) (4)	22 Apr 2021 14:42:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	22 Apr 2021 14:42:06
User opened query 'PV Re-Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 12:58:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:44:27
User entered 'None (NONE)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:39:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Other action taken is 'NONE' however, there is corresponding Concomitant Medication records (#9, #10, #11, #12, #13 and 14) for 'DOG BITE'? Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:54:47
Query 'Per CDM: Other action taken is 'NONE' however, there is corresponding Concomitant Medication records (#9, #10, #11, #12, #13 and 14) for 'DOG BITE'? Please review and reconcile accordingly.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:52:43
User entered '0' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:52:26
User opened query 'Per CDM: Other action taken is 'NONE' however, there is corresponding Concomitant Medication records (#9, #10, #11, #12, #13 and 14) for 'DOG BITE'? Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:10:36
Query 'Per CDM: Other action taken is 'NONE' however, there is corresponding Concomitant Medication records (#7, #10, #11, #12, #13 and 14) for 'DOG BITE'? Please review and reconcile accordingly.' canceled (Site from DM).		14 Apr 2021 09:10:20
User opened query 'Per CDM: Other action taken is 'NONE' however, there is corresponding Concomitant Medication records (#7, #10, #11, #12, #13 and 14) for 'DOG BITE'? Please review and reconcile accordingly.' (Site from DM).		14 Apr 2021 09:10:04
User closed query 'PV Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' (Site from Safety).		12 Apr 2021 14:17:21
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		11 Apr 2021 13:45:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

None

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' answered with 'Updated ' (Site from Safety).	(b) (4), (b) (6)	11 Apr 2021 13:44:49
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). DataPoint Un-verified.	System	11 Apr 2021 13:44:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	1 Apr 2021 13:44:24
DataPoint Verified.	(b) (4), (b) (6)	9 Apr 2021 16:46:09
User opened query 'PV Query: Please consider updating the action taken with study drug from none to not applicable as the subject had received two doses of study drug prior to the event.' (Site from Safety).	(b) (4), (b) (6)	2 Mar 2021 19:47:16
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:39:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Un-verified.	(b) (4)	
	Dawn Killian (b) (4)	14 Apr 2021 15:52:26
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	14 Apr 2021 15:52:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 16:46:10
User entered '0'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:39:23
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:07:53
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'Updated ' (Site from DM).		11 Apr 2021 13:46:44
DataPoint Un-verified.		11 Apr 2021 13:45:48
User entered '0' reason for change: Data Entry Error		11 Apr 2021 13:45:48
DataPoint Verified.		09 Apr 2021 16:44:33
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).		22 Mar 2021 12:47:54
User entered '1'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07



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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:40:17
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:15:58
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	22 Apr 2021 18:05:32
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
Signature has been broken.	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	22 Apr 2021 18:04:42
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 12:59:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		21 Apr 2021 12:58:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		21 Apr 2021 12:58:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Per source, AE is not resolved. please review and reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:35:48
		16 Apr 2021 20:35:47
User signature succeeded.	(b) (4)	16 Apr 2021 14:03:14
User closed query 'PV Query: Please confirm if the event was recovered on 03 Mar 2021 as the patient was hospitalized due to bleeding from the event. Please provide the event end date and final outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:17:16
Query 'Per source, AE is not resolved. please review and reconcile.' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	11 Apr 2021 13:46:09
Query 'PV Query: Please confirm if the event was recovered on 03 Mar 2021 as the patient was hospitalized due to bleeding from the event. Please provide the event end date and final outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'Updated ' (Site from Safety).		11 Apr 2021 13:45:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 13:43:04
User opened query 'Per source, AE is not resolved. please review and reconcile.' (Site from CRA).		09 Apr 2021 16:46:48

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the event was recovered on 03 Mar 2021 as the patient was hospitalized due to bleeding from the event. Please provide the event end date and final outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:48:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:18
User entered empty.	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[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)	22 Apr 2021 19:16:27
User closed query 'PV Re-Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Apr 2021 19:16:20
Query 'PV Re-Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Emailed to address above on 22APR2021 @ 1025am' (Site from Safety).	Antonio Gutierrez (b) (4)	22 Apr 2021 15:26:08
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 'No testing or results for COVID-19 present in records received.' (Site from Safety).	Antonio Gutierrez (b) (4)	22 Apr 2021 14:57:21
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)	21 Apr 2021 13:03:55
User opened query 'PV Re-Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		21 Apr 2021 13:02:51

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4)	12 Apr 2021 14:17:12
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:17:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated ' (Site from Safety).	(b) (4), (b) (6)	11 Apr 2021 13:48:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Updated ' (Site from Safety).	(b) (4), (b) (6)	11 Apr 2021 13:47:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:22

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:49:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		12 Mar 2021 19:49:11
User entered 'Subject stated he was attacked by a dog on 03Mar2021, he was bitten on his R arm below the elbow and had to be admitted to BAMC on 04Mar2021 due to continuous bleeding, they performed a procedure to debride the wound and pack it. He is pending to be discharged later. Medical records will be requested. AE log updated. Unk procedure, pending medical records.'	Nathan Cortez (b) (4)	05 Mar 2021 22:50:07

US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 22:50:07



US3292128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 22:50:07

**US3292128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 22:50:07

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:22:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
DataPoint Verified.	(b) (4)	27 Aug 2020 18:01:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:48:20

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:56:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:56:47

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:51
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 17:50:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 17:50:12
Data point term sent to Coder	System	12 Aug 2020 17:49:13
User entered 'Centrum silver'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:37:44
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:49:56
DataPoint Un-verified.	Dawn Killian (b) (4)	14 Apr 2021 15:49:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:49:50
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:06:35
DataPoint Verified.		27 Aug 2020 18:05:43
User entered 'No (N)'		12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Supplement'	(b) (4), (b) (6)	12 Aug 2020 17:49:00



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	7 Aug 2020 18:05:43
User entered 'l'	(b) (4), (b) (6)	2 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'tablet (TABLET)'		12 Aug 2020 17:49:00

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		12 Aug 2020 17:49:10
answered with 'medication is ongoing' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:49:00
User entered 'un UNK 2005'	(b) (4), (b) (6)	12 Aug 2020 17:49:00



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:49:00

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:49:00

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:49:00

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:49:00

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Sep 2020 16:04:50
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 16:04:50
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:04:10 24 Sep 2020 16:03:50
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:51:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:51:14
Data point term sent to Coder User entered 'Allopurinol'	System (b) (4), (b) (6)	12 Aug 2020 17:50:14 12 Aug 2020 17:49:43



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	19 Jan 2021 19:26:42
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:42:14
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 16:03:55
DataPoint Un-verified.	(b) (4)	24 Sep 2020 16:03:50
User entered 'generalized GOUT' reason for change:	Dawn Killian (b) (4)	24 Sep 2020 16:03:50
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:43:29
DataPoint Verified.		7 Aug 2020 18:05:43
User entered 'Gout'		2 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '300'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 17:49:43



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:38:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:49:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:49:43
User entered 'un UNK 2004'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 17:49:55
User entered 'No (N)'		12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Aug 2020 17:49:55
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Aug 2020 17:49:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per source this was not taken for a solicited event. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:26:54
DataPoint Verified.		19 Jan 2021 19:26:51
Query 'Per source this was not taken for a solicited event. Please review and clarify. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	27 Aug 2020 20:14:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Aug 2020 20:14:11
DataPoint Un-verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:57
DataPoint Verified.		27 Aug 2020 18:05:43
User opened query 'Per source this was not taken for a solicited event. Please review and clarify. ' (Site from CRA).		27 Aug 2020 18:02:38
User entered 'Yes (Y)'		12 Aug 2020 17:49:43

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:49:43

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:49:43



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:49:43

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 17:52:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 17:52:15
Data point term sent to Coder User entered 'Atenolol'	System (b) (4), (b) (6)	12 Aug 2020 17:51:18 12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Hypertension'		12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '25'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:22:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:50:40



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	12 Aug 2020 17:50:47
answered with 'medication is ongoing' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:50:40
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Yes (Y)'		12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:50:40



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:50:40

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:50:40

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:50:40

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 07:51:16
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 Aug 2020 07:51:16
Data point term sent to Coder	System	12 Aug 2020 17:52:19
User entered 'Calc Carb + D'	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 09:33:23
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 21:09:16
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	01 Apr 2021 21:09:08
User entered 'Yes (Y)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	01 Apr 2021 21:09:08
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:38:44
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'No (N)'		12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Supplement'	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	19 Jan 2021 19:27:18
User closed query 'Per DM CLR: Please remove and record the dose unit MG/IU in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:50:14
Query 'Per DM CLR: Please remove and record the dose unit MG/IU in the dose unit section. Please update dose and dose unit as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	26 Oct 2020 18:02:41
User entered '600/400' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 18:02:30
User entered '600/ 400' reason for change: Data Entry Error	Dawn Killian (b) (4)	26 Oct 2020 18:02:21
User opened query 'Per DM CLR: Please remove and record the dose unit MG/IU in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:33:00
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:42:38
DataPoint Un-verified.	Dawn Killian (b) (4)	24 Sep 2020 16:05:45
User entered '600 mg/ 400' reason for change: Data Entry Error	(b) (4)	24 Sep 2020 16:05:40
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 16:05:40
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 03:46:02
	(b) (4), (b) (6)	27 Aug 2020 18:05:43

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	(b) (4), (b) (6)	12 Aug 2020 17:51:26



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 19:27:11
DataPoint Un-verified.	Dawn Killian (b) (4)	26 Oct 2020 18:02:21
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Dawn Killian (b) (4)	26 Oct 2020 18:02:21
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'IU (IU)'		12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 19:27:14
DataPoint Un-verified.	Dawn Killian (b) (4)	26 Oct 2020 18:02:21
	(b) (4)	
User entered 'mg/IU' reason for change: Data Entry Error	Dawn Killian (b) (4)	26 Oct 2020 18:02:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered empty.		12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'		12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	2 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	12 Aug 2020 17:51:36
answered with 'medication is ongoing' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:51:26
User entered 'un UNK 2015'	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:51:26



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'No (N)'		12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:51:26

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:51:26

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:53:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:53:17
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	12 Aug 2020 17:52:19 12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:52:16



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Hypertension'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '10'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:52:16



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	12 Aug 2020 17:52:22
answered with 'medication is ongoing' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:52:16
User entered 'un UNK 2015'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Yes (Y)'		12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:52:16

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 17:52:16

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:52:16

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:52:16

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:52:16



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:55:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:55:21
Data point term sent to Coder User entered 'Lipitor'	System (b) (4), (b) (6)	12 Aug 2020 17:54:25 12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 17:53:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 17:53:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 17:53:45
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 17:53:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '80'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered empty.		12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:53:37



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'		12 Aug 2020 17:53:37

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	12 Aug 2020 17:53:53
answered with 'medication is ongoing' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:53:37
User entered 'un UNK 2016'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Yes (Y)'		12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered empty.		12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'No (N)'		12 Aug 2020 17:53:37

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 17:53:37



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:53:37

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:53:37

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:05:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:00:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:00:28
Data point term sent to Coder	System	17 Aug 2020 03:34:56
User entered 'colecalfiferol'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'No (N)'		17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). DataPoint Verified.	(b) (4), (b) (6) Dawn Killian (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 11:42:55 24 Sep 2020 16:07:53 18 Sep 2020 03:46:50 27 Aug 2020 18:05:43
User entered 'Vitamin D deficiency'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 19:28:01
User closed query 'Dosage, frequency and route missing from source. Please enter in source and update in EDC to reflect correct data. ' (Site from CRA).		19 Jan 2021 19:27:58
Query 'Dosage, frequency and route missing from source. Please enter in source and update in EDC to reflect correct data. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	27 Aug 2020 20:16:06
	(b) (4)	
User entered '50000' reason for change: Data Entry Error	Dawn Killian (b) (4)	27 Aug 2020 20:16:00
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:45
DataPoint Verified.		27 Aug 2020 18:05:43
User opened query 'Dosage, frequency and route missing from source. Please enter in source and update in EDC to reflect correct data. ' (Site from CRA).		27 Aug 2020 18:05:02
User entered '30000'		17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'IU (IU)'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 03:34:17



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'every month (QM)'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered 'Oral (ORAL)'		17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		17 Aug 2020 16:59:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 03:34:27
answered with 'medication is ongoing ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 03:34:17
User entered '12 Feb 2020'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query "'Stop Date or Ongoing' Field in Con med log is blank. please review and reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:12
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	19 Apr 2021 20:28:09 16 Apr 2021 14:03:14
Query "'Stop Date or Ongoing' Field in Con med log is blank. please review and reconcile.' answered with 'conmed log updated' (Site from CRA). DataPoint Un-verified.	Antonio Gutierrez (b) (4) (b) (4), (b) (6)	01 Apr 2021 21:10:14 10 Feb 2021 18:16:25
User opened query "'Stop Date or Ongoing' Field in Con med log is blank. please review and reconcile.' (Site from CRA). DataPoint Verified.		10 Feb 2021 18:16:22 27 Aug 2020 18:05:43
User entered 'Yes (Y)'		17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 18:05:43
User entered empty.		17 Aug 2020 03:34:17



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	27 Aug 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 03:34:17

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 03:34:17

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 03:34:17

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	17 Aug 2020 03:34:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:29:48
Data point term sent to Coder	System	18 Nov 2020 21:13:36
User entered 'influenza vaccine'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:40
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:41
User entered 'prophylaxis'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:16:46
User entered '0.5'	Gerardo Pena (b) (4)	18 Nov 2020 21:13:17



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:16:49
User entered 'mL (mL)'	Gerardo Pena (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:50
User entered empty.	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:54
User entered 'once (ONCE)'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:17:02
User entered empty.	Gerardo Pena (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:08
User entered empty.	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:17:12
User entered '11 Nov 2020'	Gerardo Pena (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:14
User entered '0'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17



**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:17:16
User entered 'No (N)'	Gerardo Pena (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:18
User entered '11 Nov 2020'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:22
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	18 Nov 2020 21:13:17

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User entered empty.	System	18 Nov 2020 21:13:17

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User entered empty.	System	18 Nov 2020 21:13:17

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:34
User entered empty.	System	18 Nov 2020 21:13:17

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
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: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 06:16:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:16:44
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	14 Apr 2021 15:50:36 14 Apr 2021 15:50:35
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 09:51:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 09:51:51
Data point term sent to Coder User entered 'Naproxen'	System Gerardo Pena (b) (4)	29 Mar 2021 15:25:25 29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:12
User signature succeeded.	(b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 09:50:49
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	14 Apr 2021 15:50:39
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	14 Apr 2021 15:50:35
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:08
User closed query 'Per DM CLR: Please note that there is no ongoing 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)	14 Apr 2021 09:12:08
Query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable detail to the AE eCRF as appropriate. ' answered with 'Please confirm.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:25:57
User opened query 'Per DM CLR: Please note that there is no ongoing 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)	06 Apr 2021 07:46:49
User entered 'dog bite'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '500'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'as needed (PRN)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
DataPoint Verified.		19 Apr 2021 20:31:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:24:24

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
User entered empty.	System	29 Mar 2021 15:24:24

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
User entered empty.	System	29 Mar 2021 15:24:24

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:36
User entered empty.	System	29 Mar 2021 15:24:24



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 15:58:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 15:58:39
Data point term sent to Coder	System	14 Apr 2021 15:51:39
Coding entries removed.	Dawn Killian (b) (4)	14 Apr 2021 15:50:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 15:32:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 15:32:05
Data point term sent to Coder	System	29 Mar 2021 15:28:29
User entered 'acetaminophen'	Gerardo Pena (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM). Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:50:54
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:50:50
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:50:46
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:19
User closed query 'Per DM CLR: Please note that there is no ongoing 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)	14 Apr 2021 09:12:19
Query 'Per DM CLR: Please note that there is no ongoing 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 'Please confirm.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:26:02
User opened query 'Per DM CLR: Please note that there is no ongoing 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)	06 Apr 2021 07:47:06
User entered 'dog bite'	Gerardo Pena (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '325'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'as needed (PRN)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:22:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
DataPoint Verified.		19 Apr 2021 20:31:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:28:08

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
User entered empty.	System	29 Mar 2021 15:28:08



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
User entered empty.	System	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:40
User entered empty.	System	29 Mar 2021 15:28:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 15:57:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 15:57:41
Data point term sent to Coder	System	14 Apr 2021 15:51:41
Coding entries removed.	Dawn Killian (b) (4)	14 Apr 2021 15:50:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 15:32:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 15:32:47
Data point term sent to Coder	System	29 Mar 2021 15:29:31
User entered 'Amoxicillin/clavulanic acid'	Gerardo Pena (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM). Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:50:59
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:50:59
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:50:56
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:27
User closed query 'Per DM CLR: Please note that there is no ongoing 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)	14 Apr 2021 09:12:27
Query 'Per DM CLR: Please note that there is no ongoing 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 'Please confirm.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:26:07
User opened query 'Per DM CLR: Please note that there is no ongoing 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)	06 Apr 2021 07:47:18
User entered 'dog bite'	Gerardo Pena (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '500/125'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.		19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:29:08

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
User entered 'I'	System	29 Mar 2021 15:29:08

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
User entered 'I'	System	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:42
User entered '804 (804)'	System	29 Mar 2021 15:29:08

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 05:40:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 05:40:42
Data point term sent to Coder	System	14 Apr 2021 15:51:40
Coding entries removed.	Dawn Killian (b) (4)	14 Apr 2021 15:51:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 00:49:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:49:23
Data point term sent to Coder	System	29 Mar 2021 15:30:32
User entered 'Docusate'	Gerardo Pena (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:51:03
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:51:10
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:51:05
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:34
User closed query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	14 Apr 2021 09:12:34
' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:26:11
Query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	06 Apr 2021 07:50:28
' answered with 'Please confirm.' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	
' (Site from DM).	(b) (4), (b) (6)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:22:59**

[Indication](#)

Audit	User	Time (GMT)
User entered 'dog bite'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '100'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.		19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:30:01

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
User entered 'l'	System	29 Mar 2021 15:30:01

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
User entered 'I'	System	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:44
User entered '804 (804)'	System	29 Mar 2021 15:30:01

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4)	19 Apr 2021 20:30:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 15:58:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 15:58:40
Data point term sent to Coder	System	14 Apr 2021 15:51:42
Coding entries removed.	Dawn Killian (b) (4)	14 Apr 2021 15:51:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 15:35:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 15:35:47
Data point term sent to Coder	System	29 Mar 2021 15:33:36
User entered 'hydrocodone/acetaminophen'	Gerardo Pena (b) (4)	29 Mar 2021 15:32:44



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:51:07
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:51:45
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:44
User closed query 'Per DM CLR: Please note that there is no ongoing 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).		14 Apr 2021 09:12:44
Query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable detail to the AE eCRF as appropriate.'		09 Apr 2021 16:27:38
' answered with 'Please confirm.' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no ongoing 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.'		06 Apr 2021 07:47:43
' (Site from DM).		
User entered 'dog bite'	Gerardo Pena (b) (4)	29 Mar 2021 15:32:44
	(b) (4)	

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:08
User closed query 'Per source this is 7.5/325. Please confirm and update.' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		19 Apr 2021 21:01:16
Query 'Per source this is 7.5/325. Please confirm and update.' answered with 'updated' (Site from CRA).		19 Apr 2021 21:01:14
Signature has been broken.		19 Apr 2021 20:36:54
User entered '7.5/325' reason for change: Data Entry Error		19 Apr 2021 20:36:45
User opened query 'Per source this is 7.5/325. Please confirm and update.' (Site from CRA).		19 Apr 2021 20:36:45
User signature succeeded.	Douglas Denham (b) (4)	19 Apr 2021 20:30:08
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 5/325).' (Site from DM).	(b) (4)	16 Apr 2021 14:03:14
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 5/325).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6)
User entered '75/325' reason for change: Data Entry Error		14 Apr 2021 09:13:38
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 5/325).' (Site from DM).		09 Apr 2021 16:27:36
User entered '325'	Gerardo Pena (b) (4)	09 Apr 2021 16:27:27
	(b) (4)	06 Apr 2021 07:52:55

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:18
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:19
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:22:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:32
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.		19 Apr 2021 20:30:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:36
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:32:44

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
User entered 'l'	System	29 Mar 2021 15:32:44

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
User entered 'I'	System	29 Mar 2021 15:32:44



US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:47
User entered '804 (804)'	System	29 Mar 2021 15:32:44

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 06:18:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:18:45
Data point term sent to Coder	System	14 Apr 2021 15:52:43
Coding entries removed.	Dawn Killian (b) (4)	14 Apr 2021 15:51:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 09:06:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 09:06:24
Data point term sent to Coder	System	29 Mar 2021 15:33:36
User entered 'Ondansetron'	Gerardo Pena (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User closed query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:51:14
Query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	14 Apr 2021 15:51:54
User entered 'DOG BITE R ARM' reason for change: Data Entry Error	Dawn Killian (b) (4)	14 Apr 2021 15:51:50
User opened query 'Per CDM: Please review and confirm if this pertains to 'DOG BITE R ARM (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:12:51
User closed query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	14 Apr 2021 09:12:51
Query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	09 Apr 2021 16:27:45
' answered with 'Please confirm.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:50:43
User opened query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update.'	(b) (4), (b) (6)	
' (Site from DM).	(b) (4), (b) (6)	

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:22:59**

[Indication](#)

Audit	User	Time (GMT)
User entered 'dog bite'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '4'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '5 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

**US3292128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:22:59**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '22 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21



US3292128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
DataPoint Verified.		19 Apr 2021 20:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 15:33:21

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:22:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
User entered 'I'	System	29 Mar 2021 15:33:21

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
User entered 'I'	System	29 Mar 2021 15:33:21

US3292128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:22:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:49
User entered '804 (804)'	System	29 Mar 2021 15:33:21

US3292128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:22:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:59:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:50
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	04 Feb 2021 16:22:44

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'USA-US072-2021-MRNA-1273-P301000016'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Douglas'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Denham'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '7940 Floyd Curl Drive'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'San Antonio'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '78229'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'US'	(b) (4) System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:02:20
User entered '3'	System	15 Apr 2021 14:07:40
User entered '2'	System	12 Apr 2021 14:15:27
User entered '1'	System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'USA-US072-2021-MRNA-1273-P301000016'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Douglas'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Denham'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '7940 Floyd Curl Drive'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'San Antonio'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '78229'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
Reviewed for Safety.		12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'US'	(b) (4) System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:02:20
User entered '3'	System	15 Apr 2021 14:07:40
User entered '2'	System	12 Apr 2021 14:15:27
User entered '1'	System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:22:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered '08/Mar/2021 11:08'	(b) (4) System	08 Mar 2021 16:08:28

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:22:59

**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)	12 Apr 2021 19:56:14
Reviewed for Safety.		12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'l'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'USA-US072-2021-MRNA-1273-P301000016'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Douglas'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Denham'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '7940 Floyd Curl Drive'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'San Antonio'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '78229'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
Reviewed for Safety.		12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'US'	(b) (4) System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:02:20
User entered '3'	System	15 Apr 2021 14:07:40
User entered '2'	System	12 Apr 2021 14:15:27
User entered '1'	System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:22:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:56:14
User entered '12/Apr/2021 09:15'	System	12 Apr 2021 14:15:27

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:22:59

**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.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
DataPoint Verified.	(b) (4)	12 Apr 2021 19:56:14
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 14:15:27

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'USA-US072-2021-MRNA-1273-P301000016'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Douglas'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Denham'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '7940 Floyd Curl Drive'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'San Antonio'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '78229'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
Reviewed for Safety.		12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'US'	(b) (4) System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:02:20
User entered '3'	System	15 Apr 2021 14:07:40
User entered '2'	System	12 Apr 2021 14:15:27
User entered '1'	System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:22:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered '15/Apr/2021 10:07'	(b) (4) System	15 Apr 2021 14:07:40

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:22:59

**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)	19 Apr 2021 17:03:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:14
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 14:07:40

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'USA-US072-2021-MRNA-1273-P301000016'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Yes (Y)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'No (N)'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Douglas'	System	08 Mar 2021 16:07:24



**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'Denham'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '7940 Floyd Curl Drive'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered 'San Antonio'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:08:22
User entered '78229'	System	08 Mar 2021 16:07:24

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:56:14
Reviewed for Safety.		12 Apr 2021 14:15:14
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:38
User entered 'US'	(b) (4) System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:22:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:02:20
User entered '3'	System	15 Apr 2021 14:07:40
User entered '2'	System	12 Apr 2021 14:15:27
User entered '1'	System	08 Mar 2021 16:08:28

**US3292128**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:22:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:11
User entered '22/Apr/2021 12:02'	System	22 Apr 2021 19:02:20

US3292128

Folder: SAE USA-US072-2021-MRNA-1273-P301000016

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:22:59

**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.	Douglas Denham (b) (4)	23 Apr 2021 18:32:38
DataPoint Verified.	(b) (4)	23 Apr 2021 16:02:11
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 19:02:20